09955960 "090600

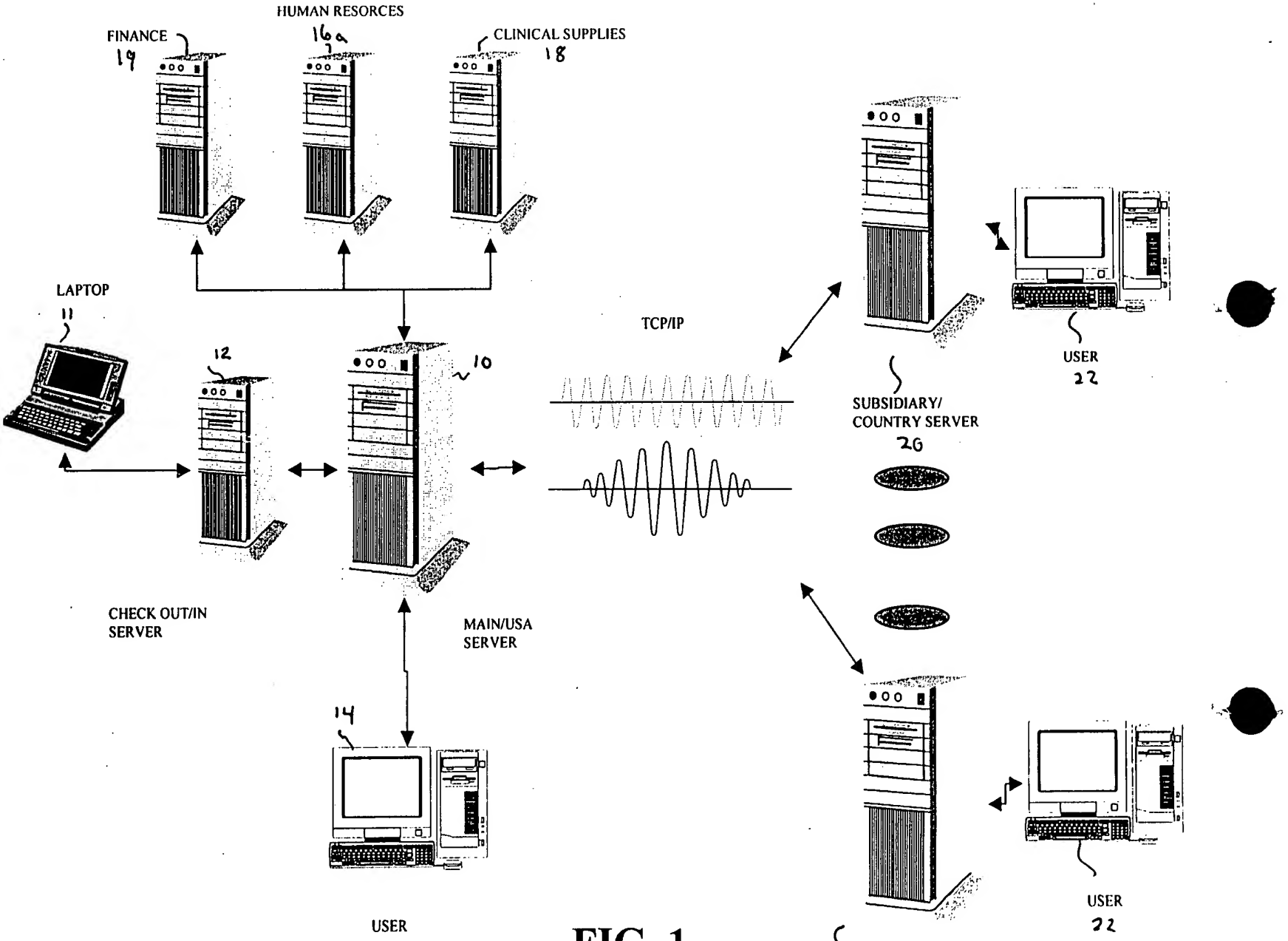


FIG. 1

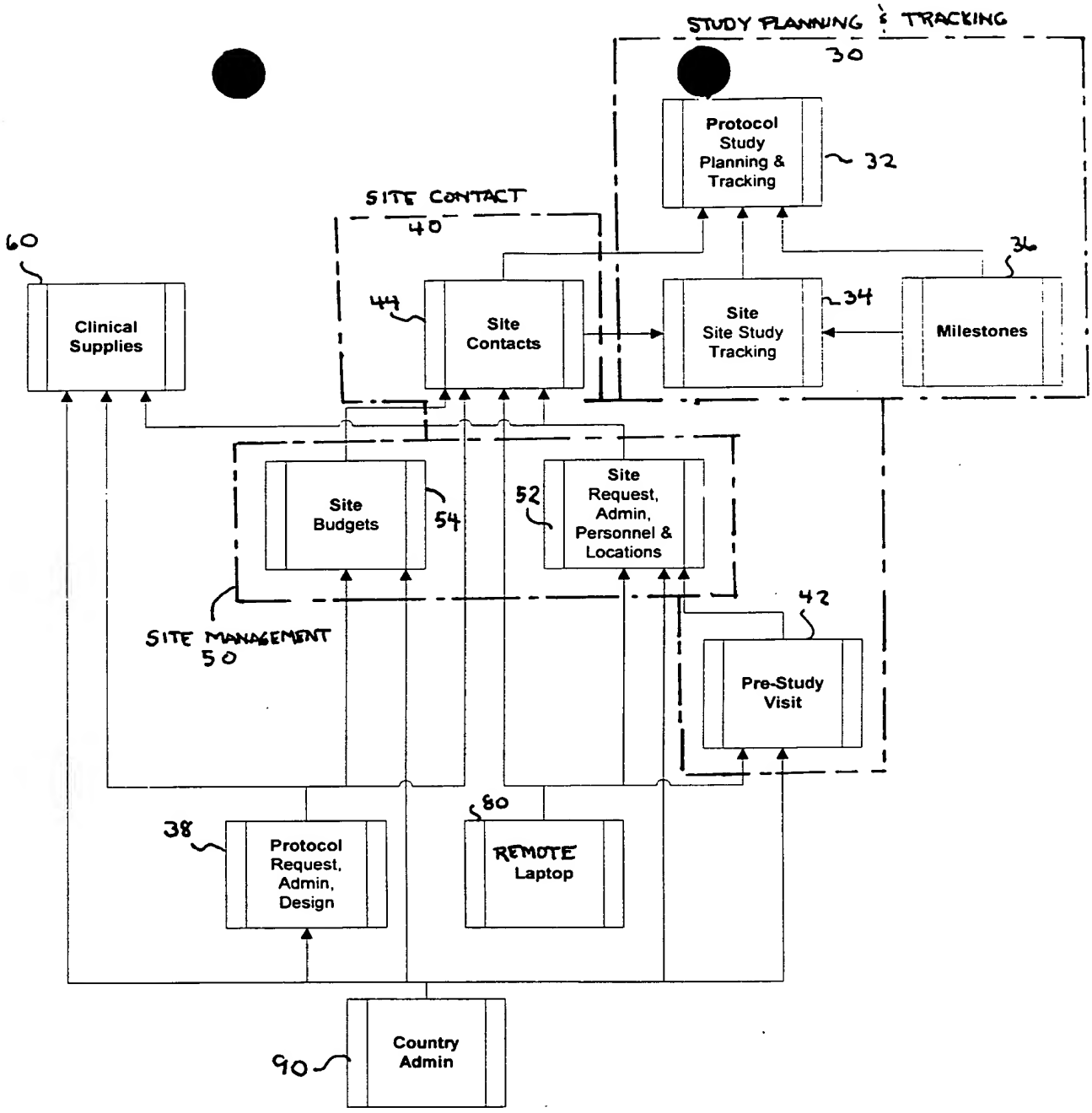
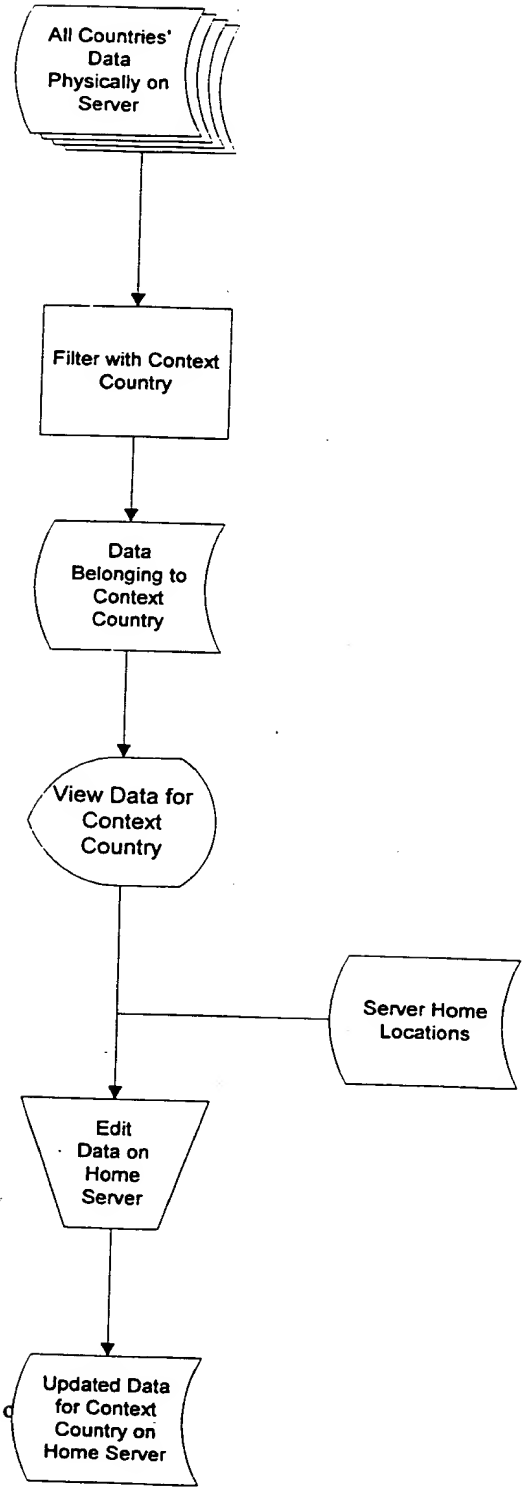

STUDY PLANNING & TRACKING
30
Protocol Study Planning & Tracking
32
SITE CONTACT
40
60
Clinical Supplies
44
Site Contacts
Site Site Study Tracking
34
36
Milestones
Site Budgets
54
52
Site Request, Admin, Personnel & Locations
SITE MANAGEMENT
50
42
Pre-Study Visit
38
Protocol Request, Admin, Design
80
REMOTE Laptop
90
Country Admin

FIG. 2

Data Flow Diagram

Module: **Architecture**
Section: **Multi-Country**

Fig. 3



D955959 D95059

THE PROTOCOL NUMBER REQUEST SCREEN

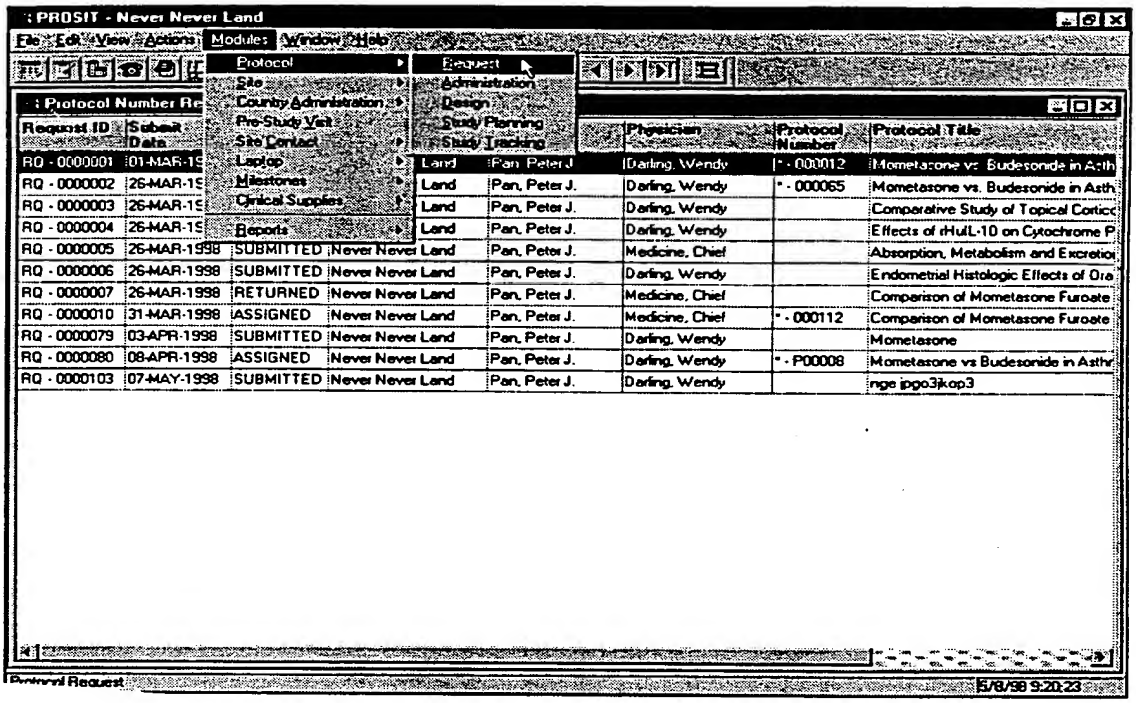
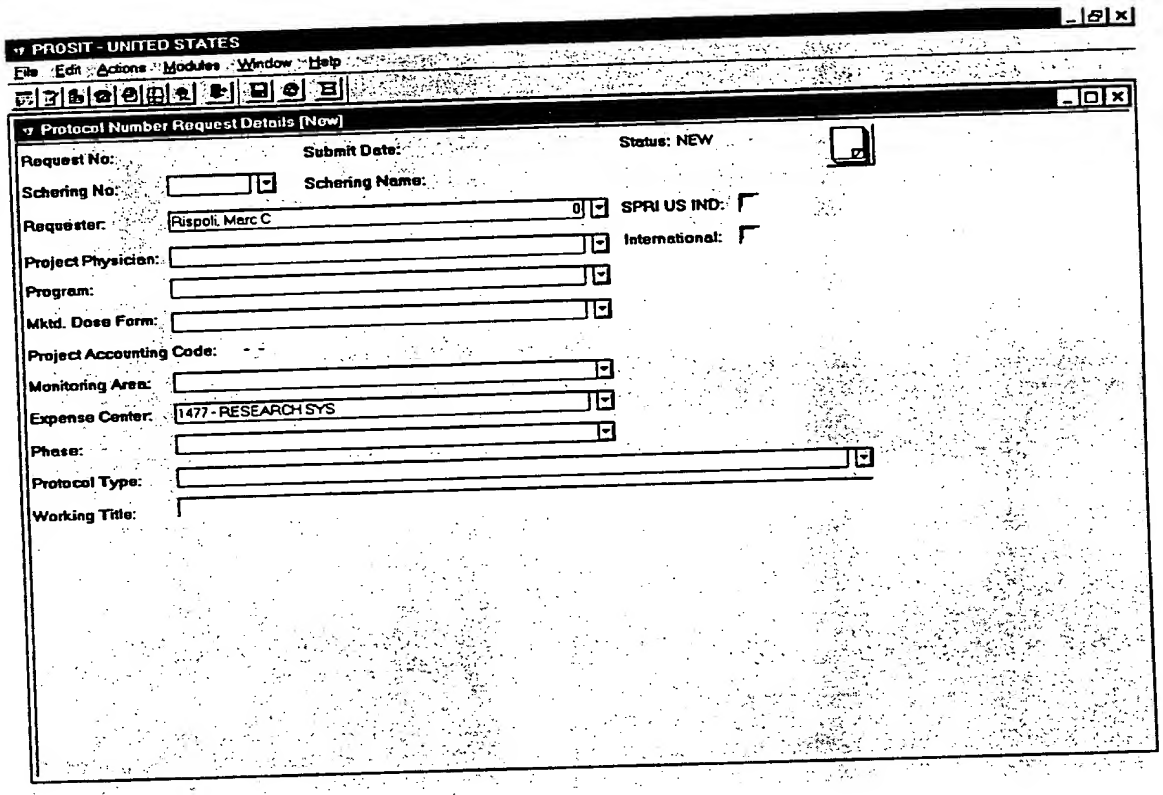


Fig. 4

0955969 - 0955969


PROSIT - UNITED STATES
File Edit Actions Modules Window Help
Protocol Number Request Details [New]
Request No:
Submit Date:
Status: NEW
Schering No:
Schering Name:
Requester:
Rispoli, Marc C
SPRI US IND:
International:
Project Physician:
Program:
Mktd. Dose Form:
Project Accounting Code:
Monitoring Area:
Expense Center:
1477 - RESEARCH SYS
Phase:
Protocol Type:
Working Title:

0055055

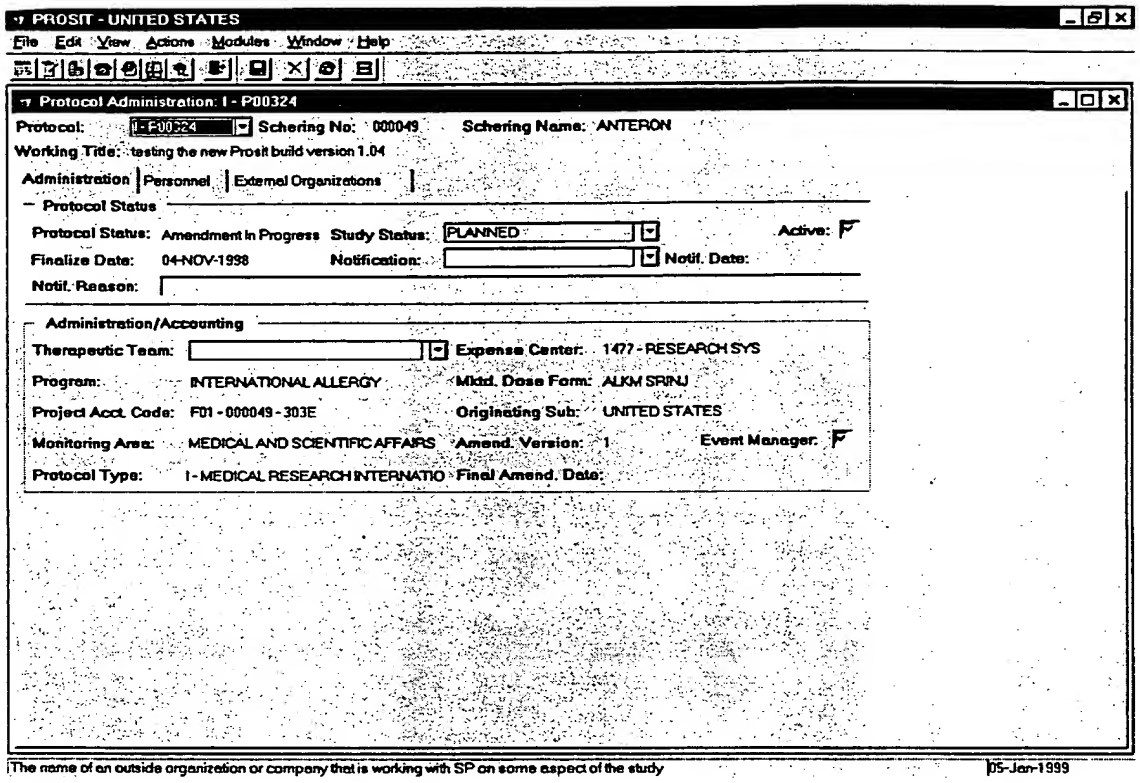
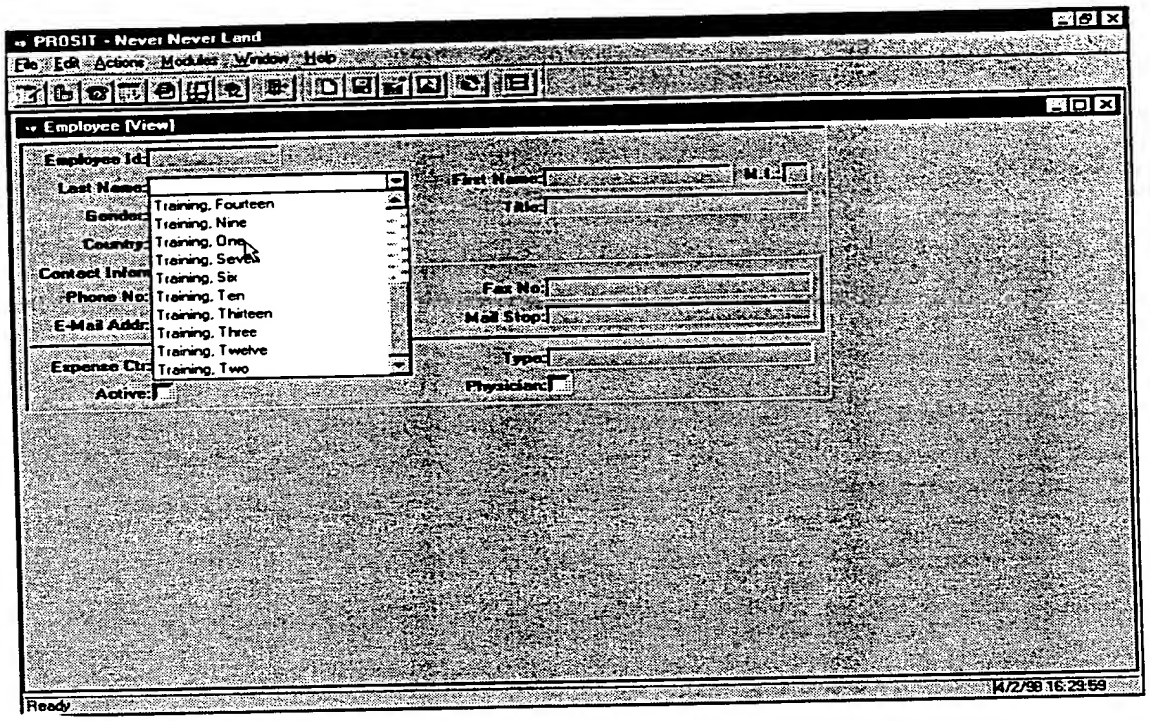


Fig. 6

5955950 "05050

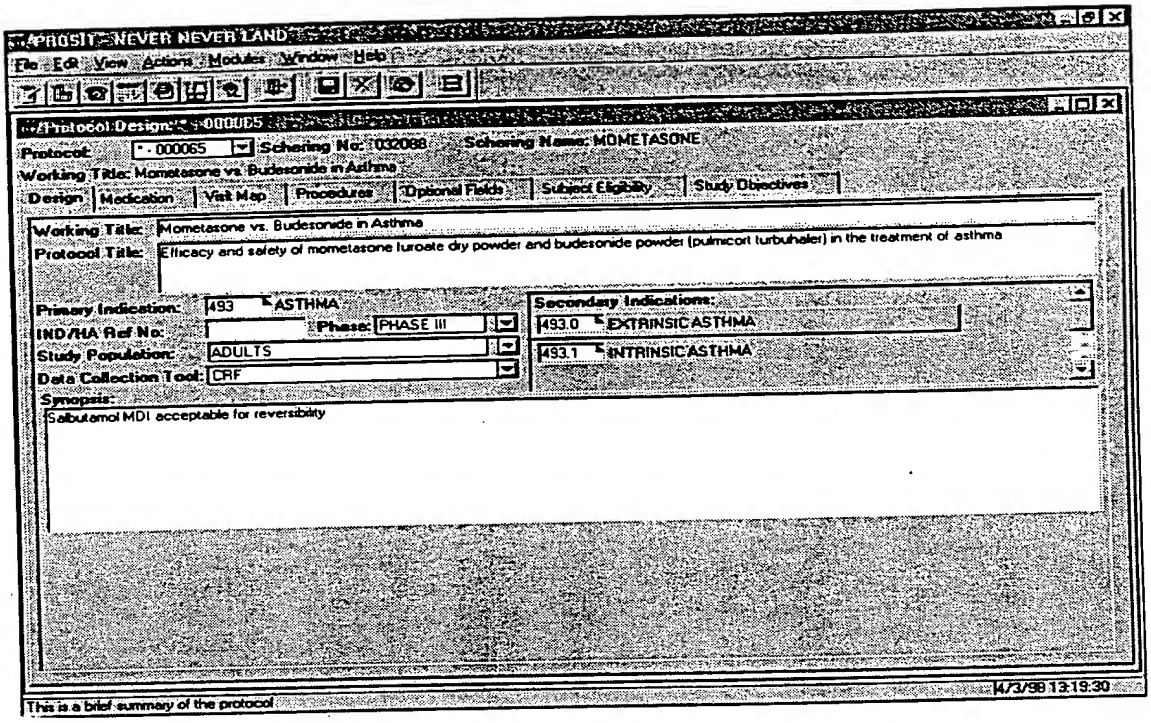
EMPLOYEE ROSTER SCREEN



F.S. 7

0090050 .0055950

PROTOCOL DESIGN



F 5.8

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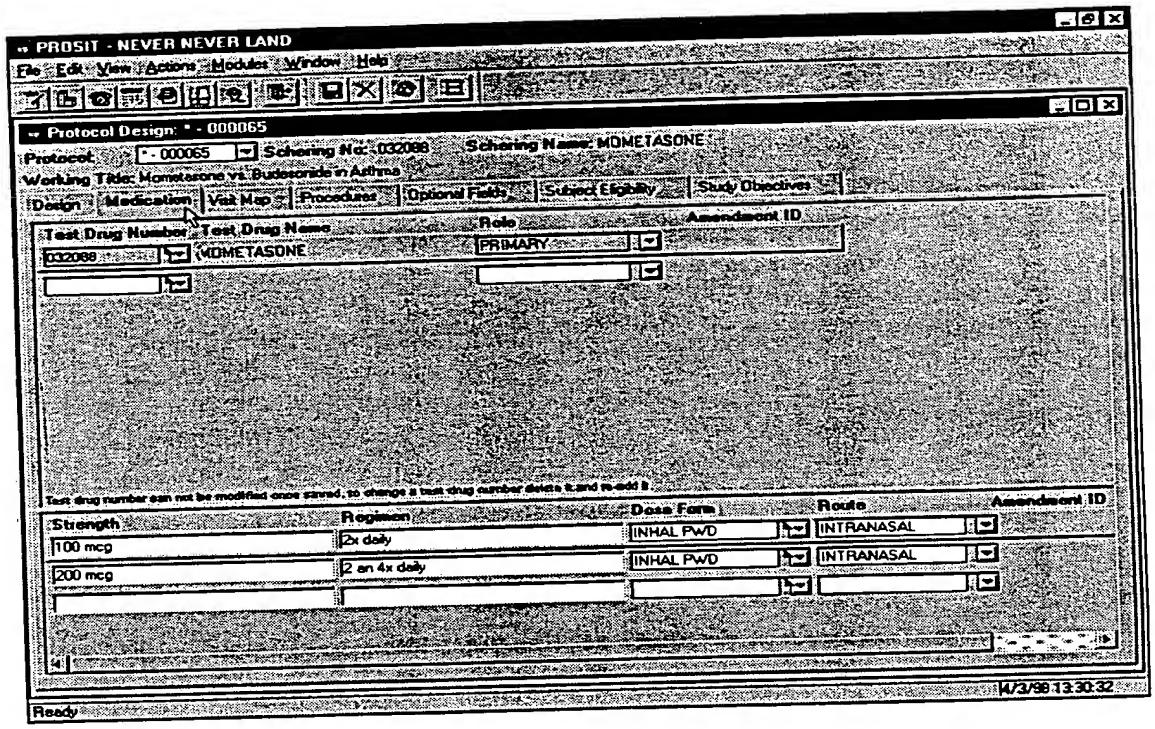
THE MEDICATION TAB



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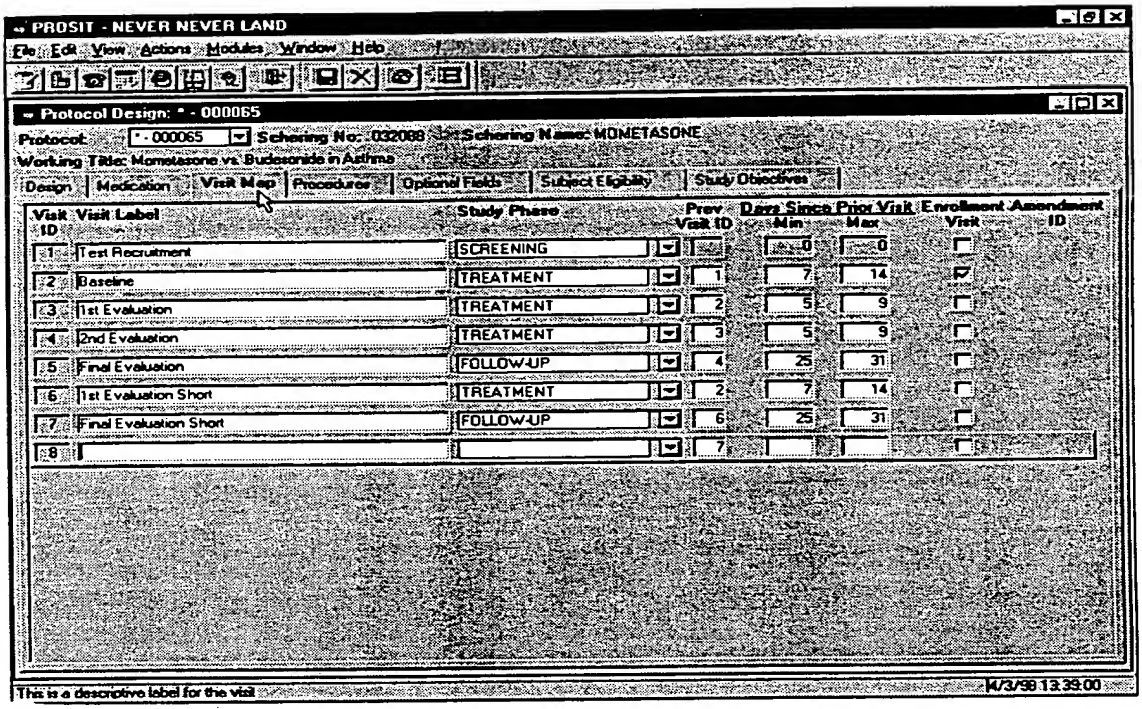
A1
3.9

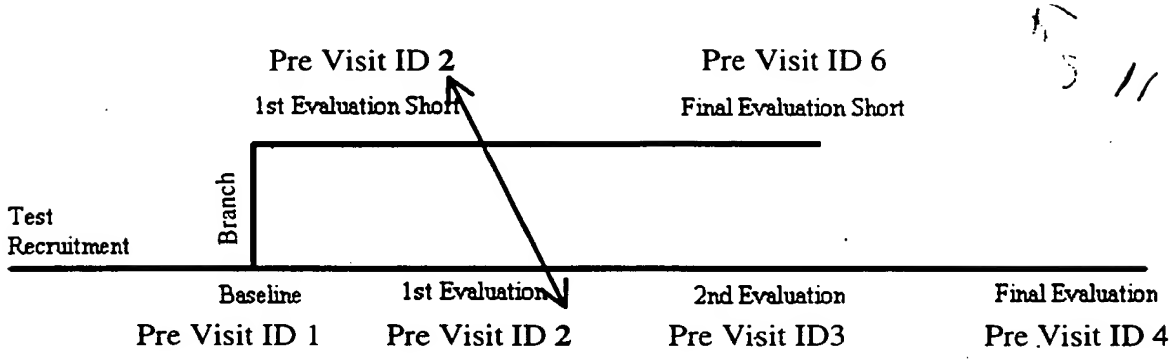
VISIT MAP



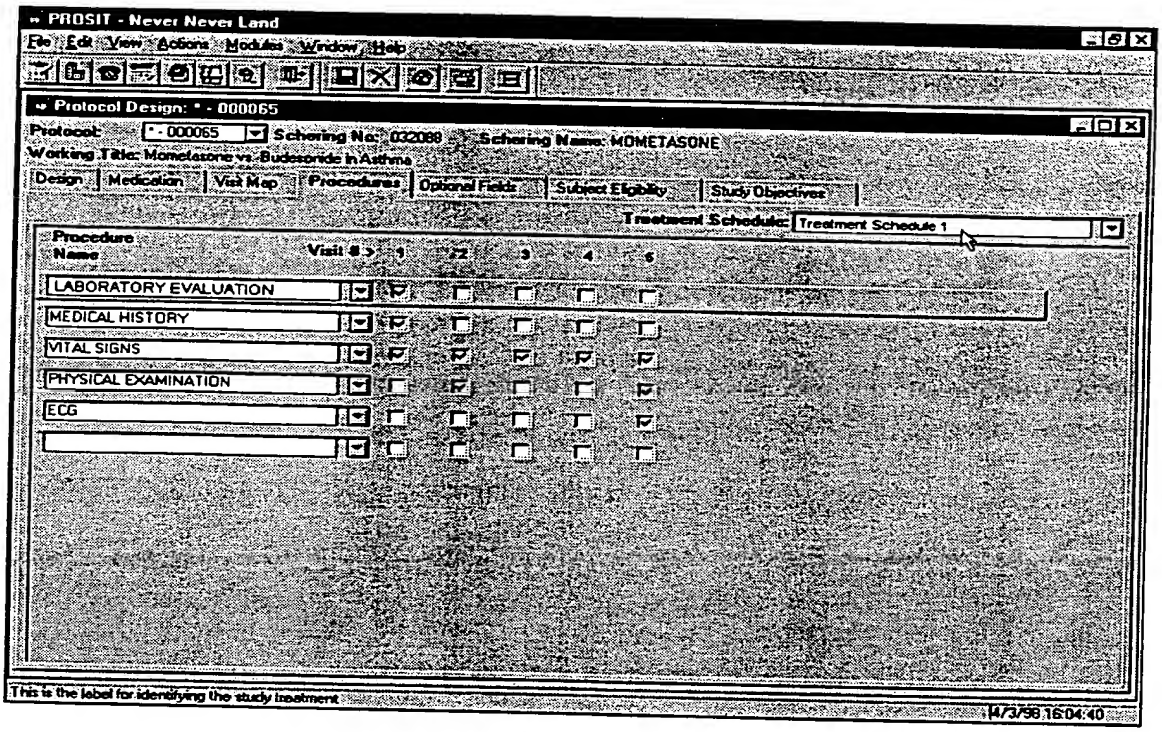
F-510

0055557 0055557

DIFFERENT TREATMENT SCHEDULES CONT.



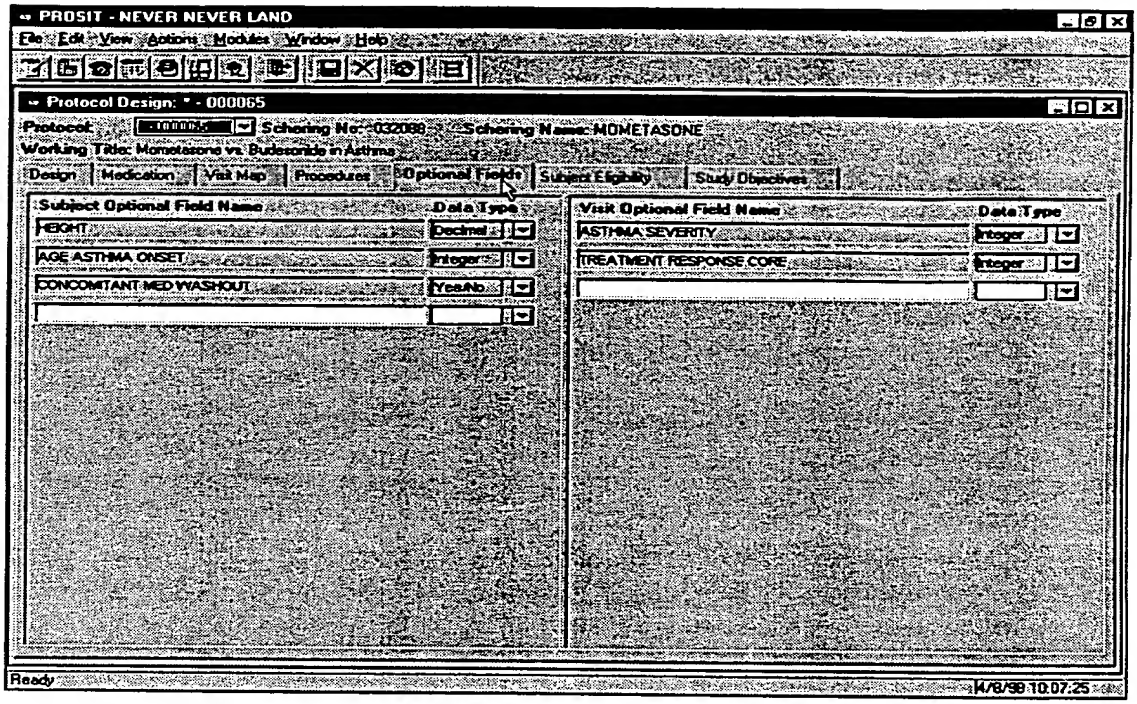
PROCEDURES TAB



F.5.12

0055555 - 0055555

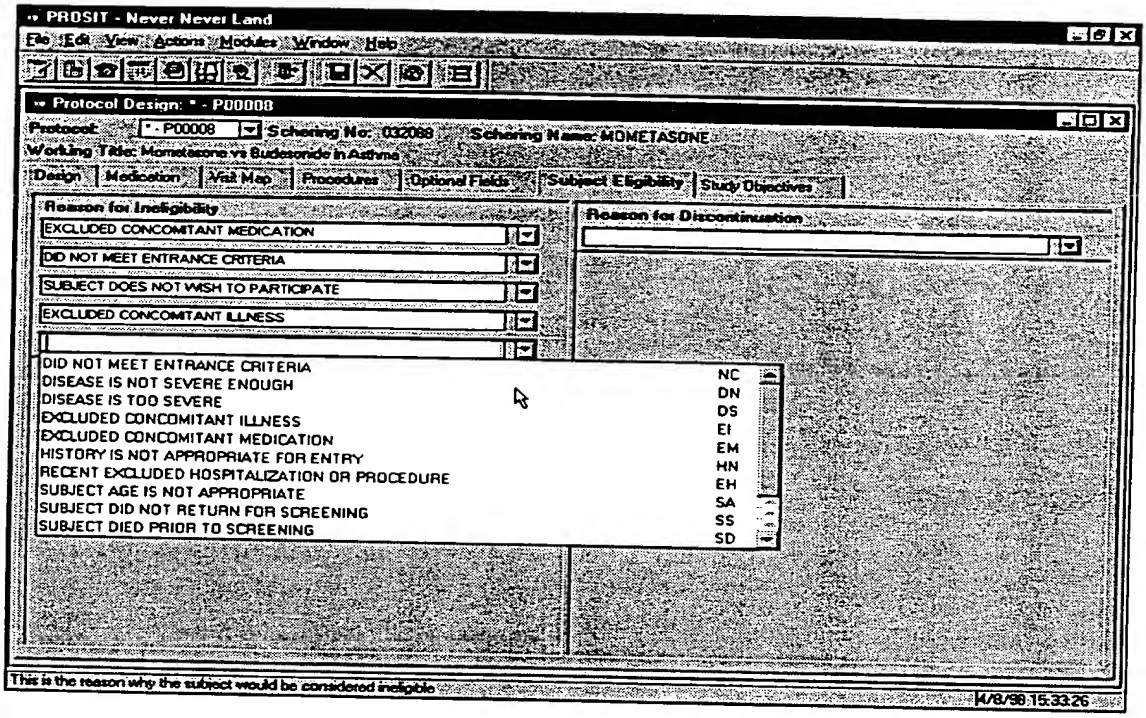
OPTIONAL FIELDS



T.S. 13

0055555-005555

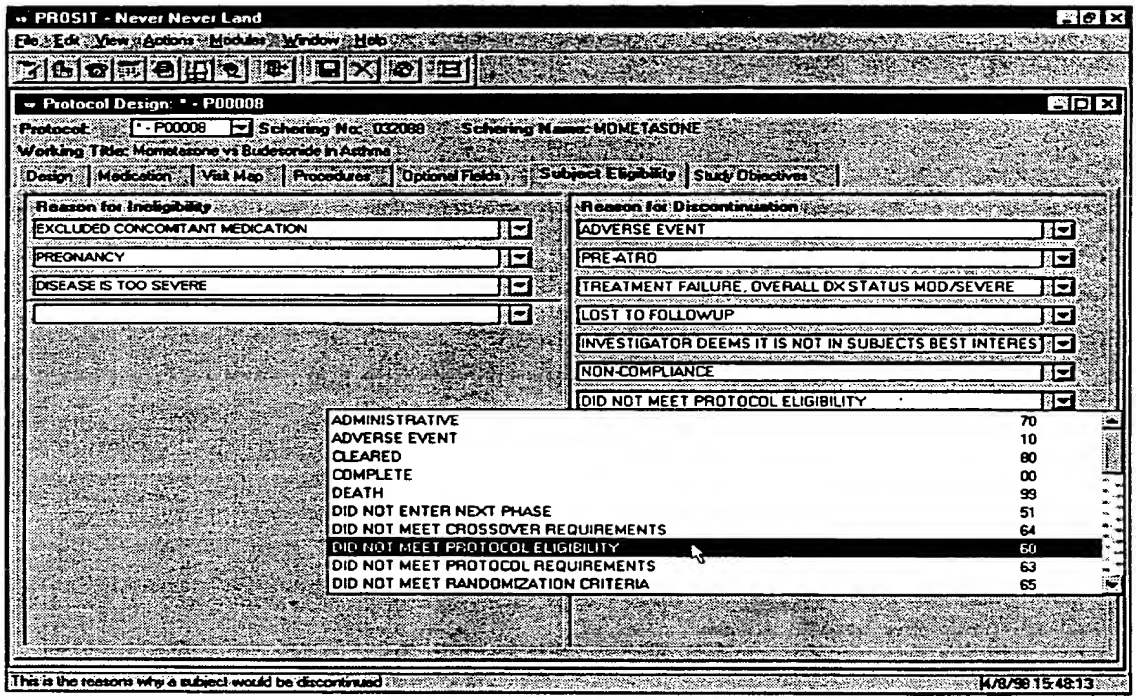
SUBJECT ELIGIBILITY



0055503

F.5.14

REASONS FOR DISCONTINUATION CONT.



F.5.15

0055055 0055055

DESIGN CONSIDERATIONS

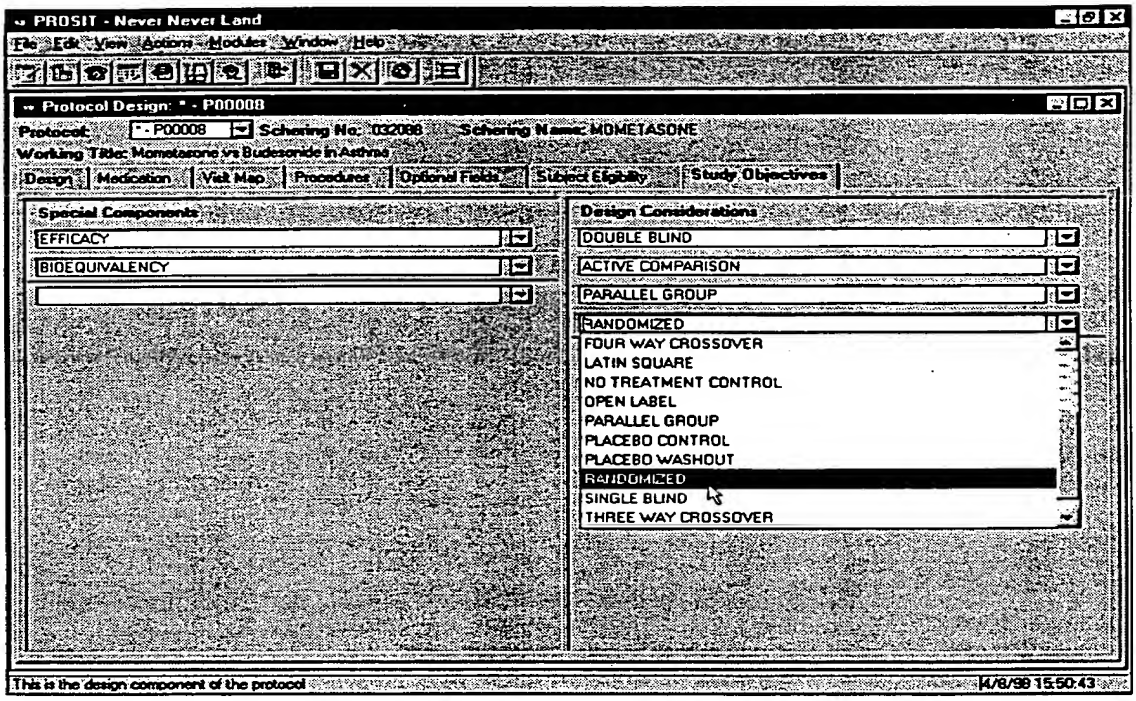


Fig. 1C

0055555.0050

CREATING AN AMENDMENT

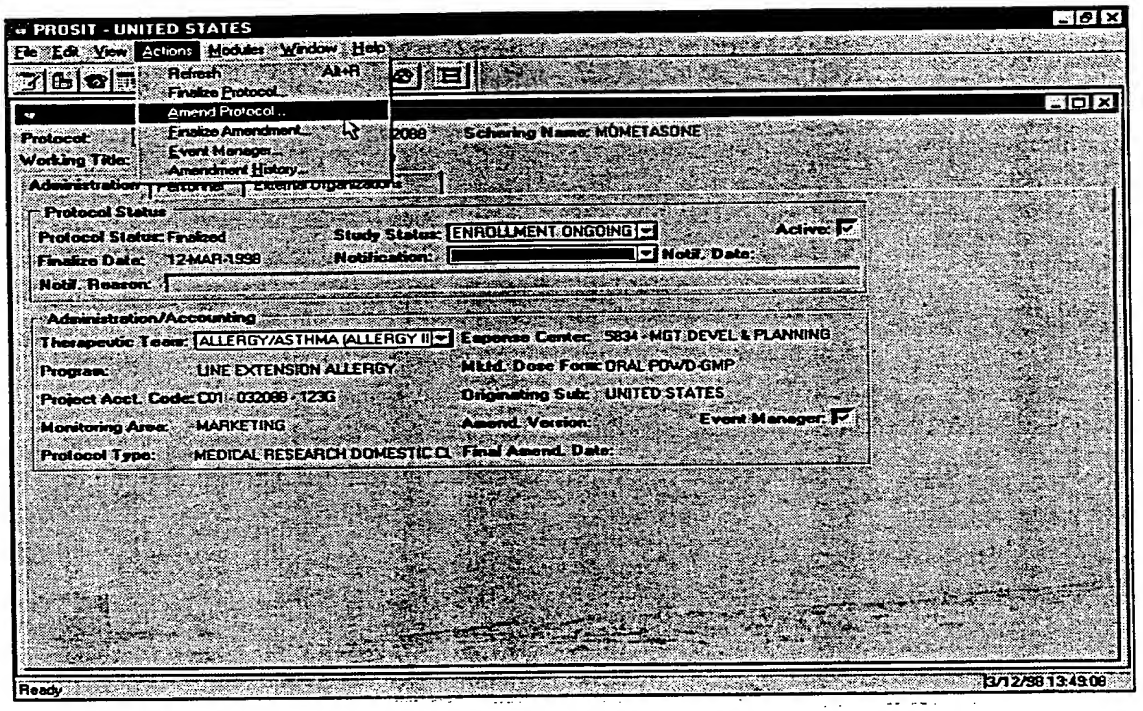


Fig. 17

05555750 05555750

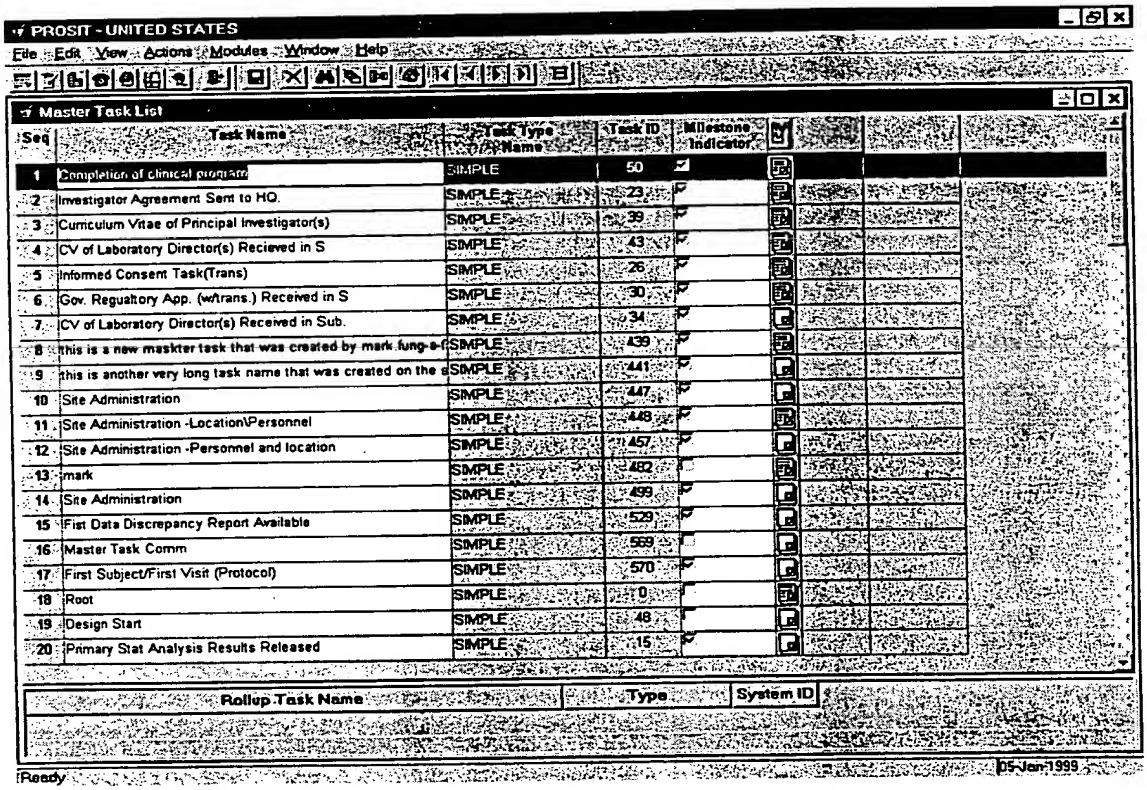


Fig. 18

0555507.0500

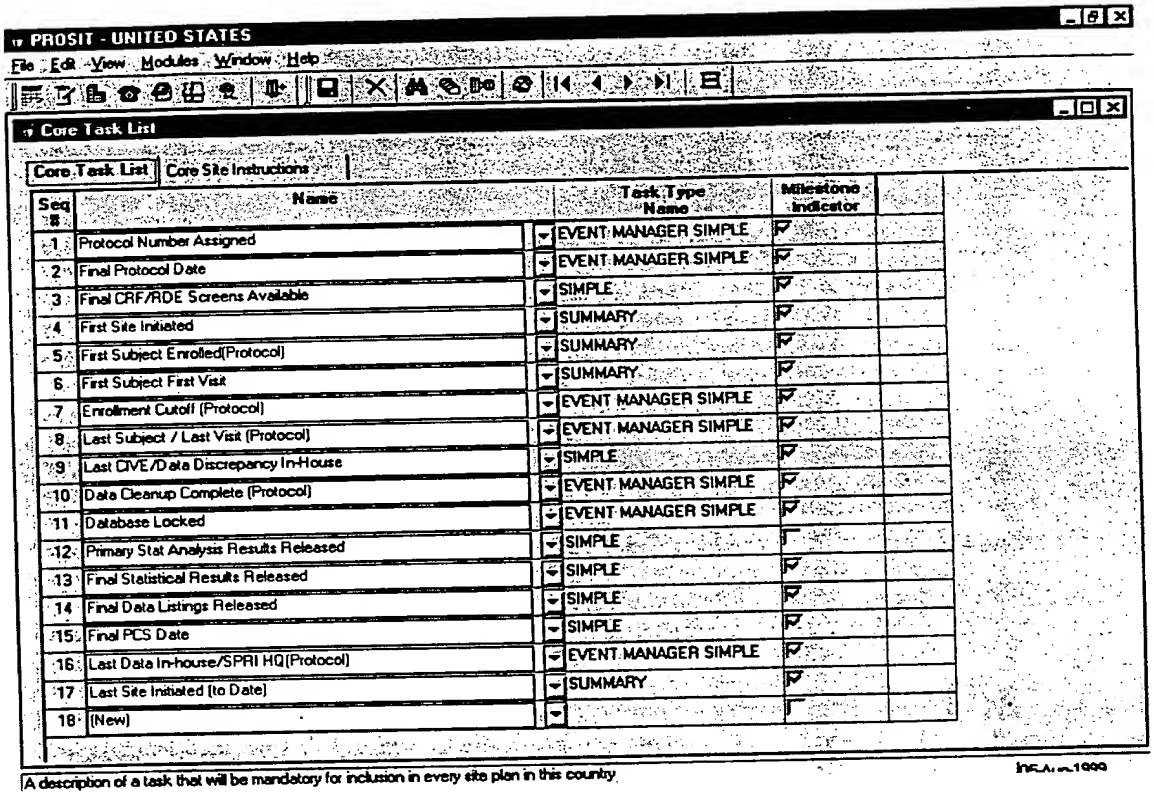
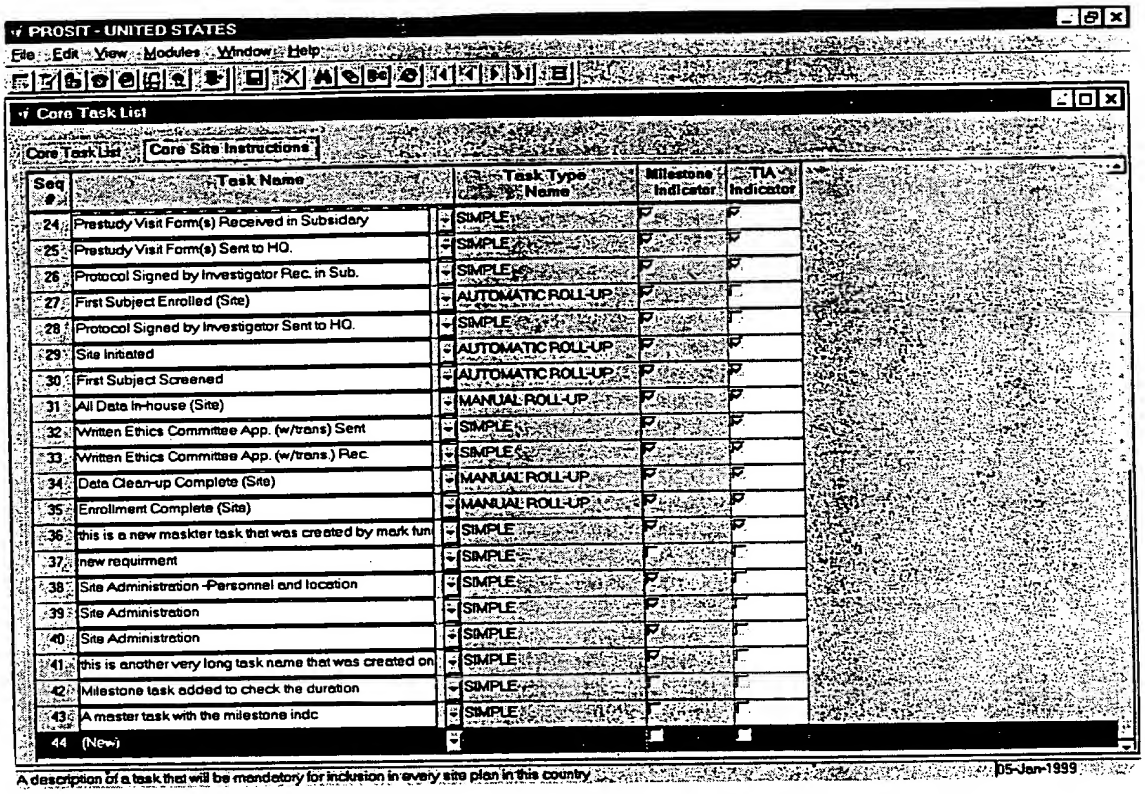


Fig 19

0055555 - 0055555



A1
8.20

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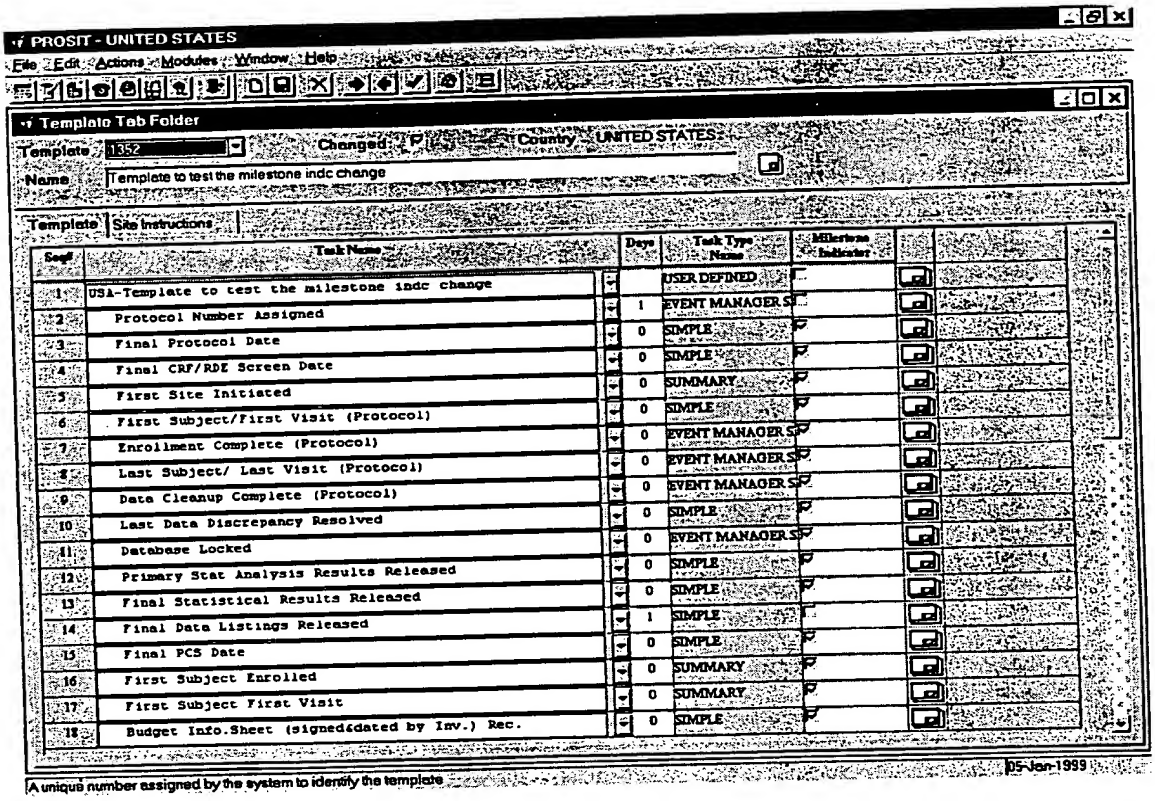


Fig. 21

0005050 "3555050

SELECTING A TEMPLATE

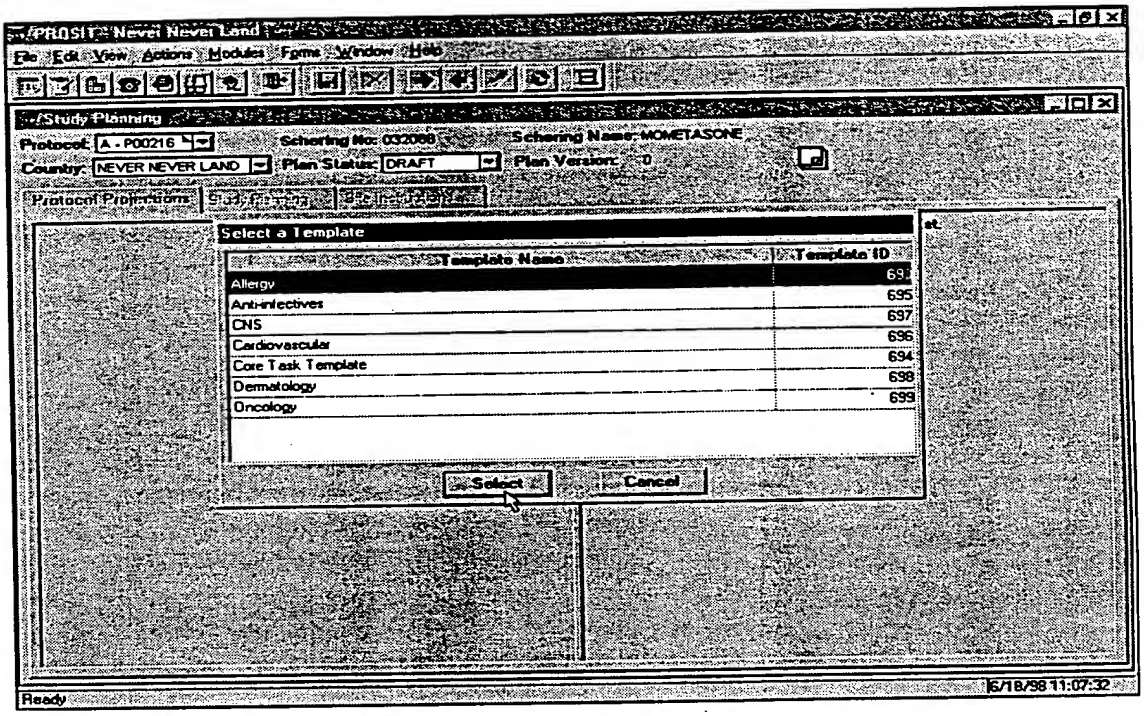
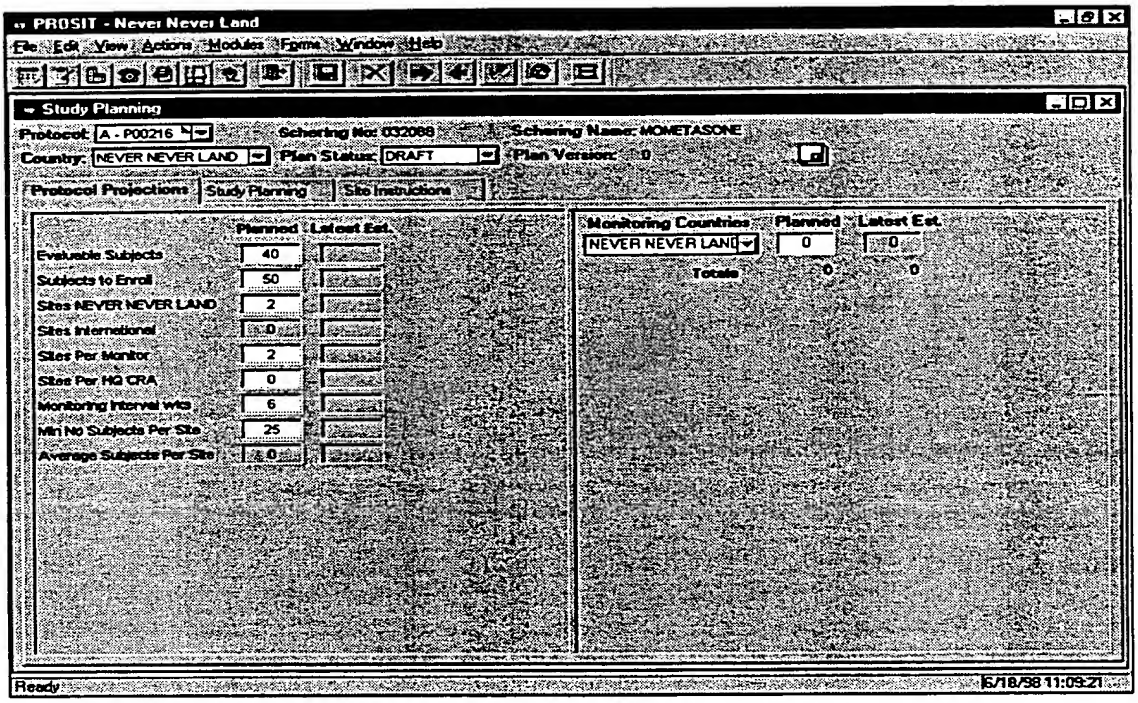


FIG. 22

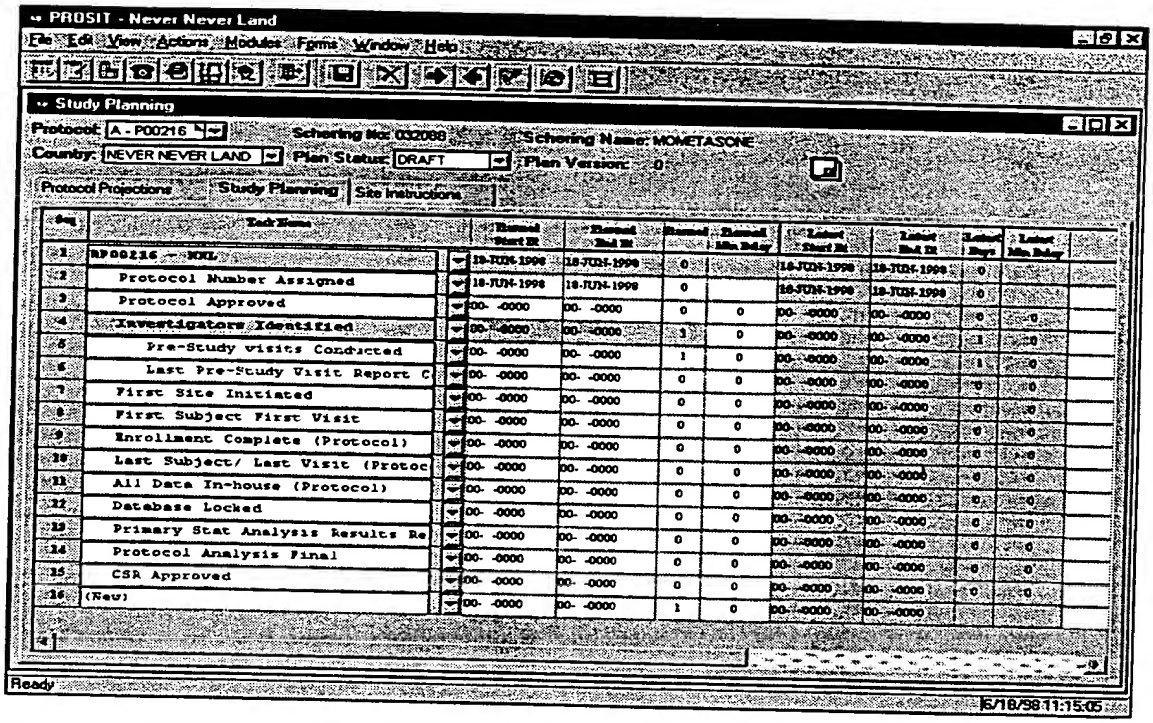
0055003

PROTOCOL PROJECTION TAB



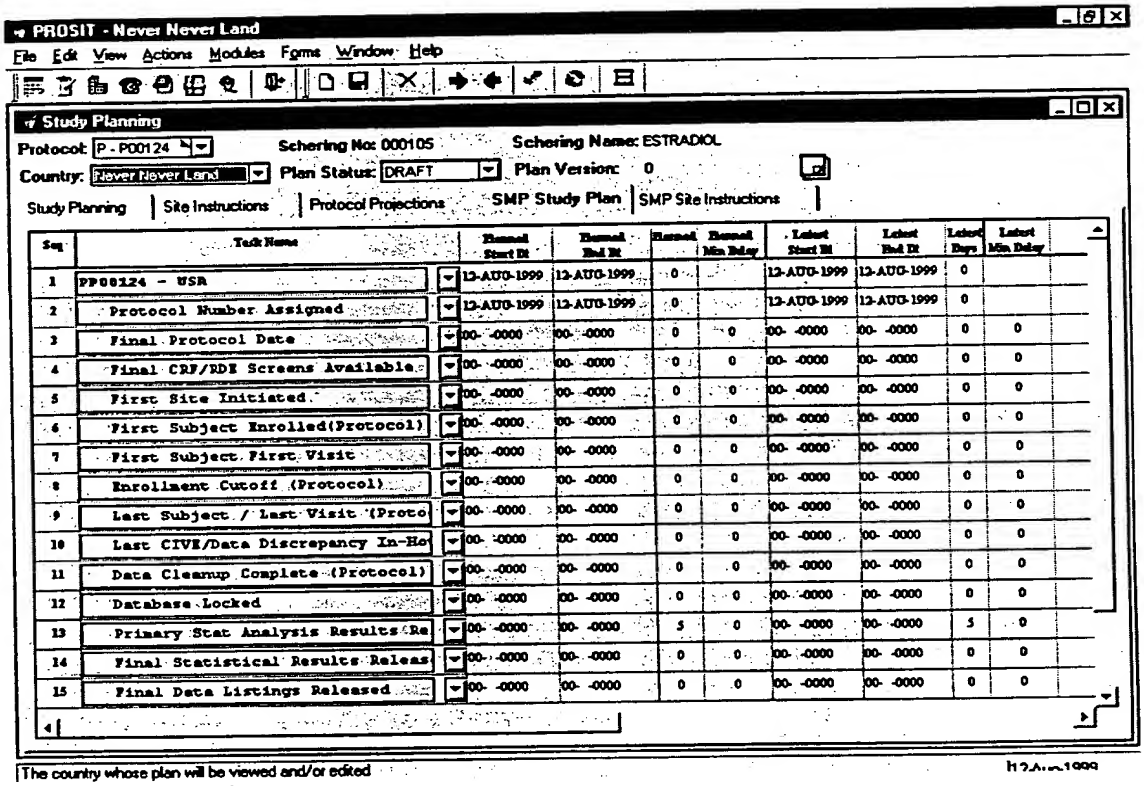
0050950 - 0050950

STUDY PLAN



F.S 24

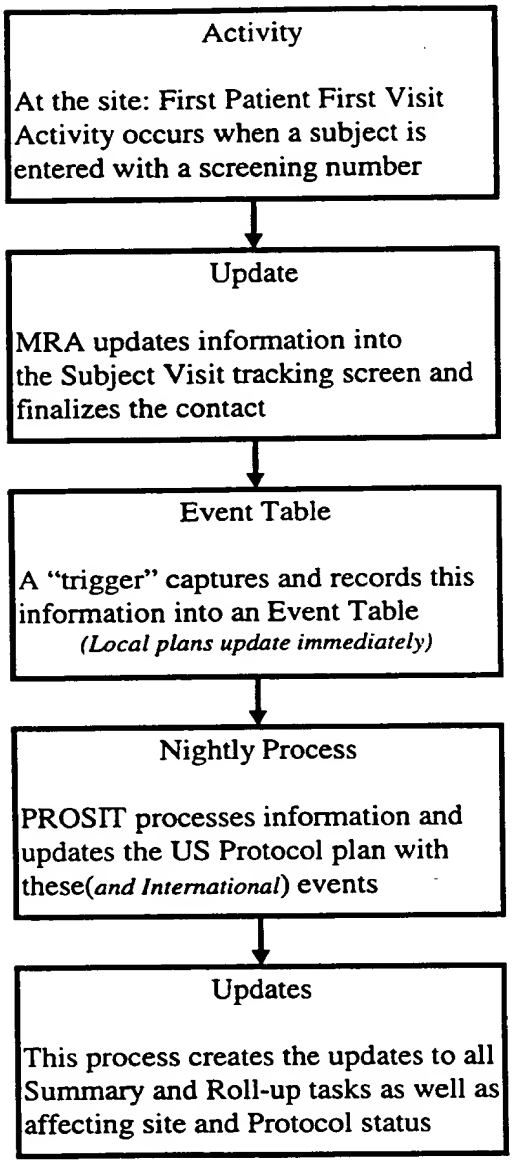
0090950 2395950



F-S 25

0550 - 0550

THE EVENT MANAGER



A. 9. 26

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Module: Event Manager

PROSIT driven for:

- Planned/Protocol Number Assigned

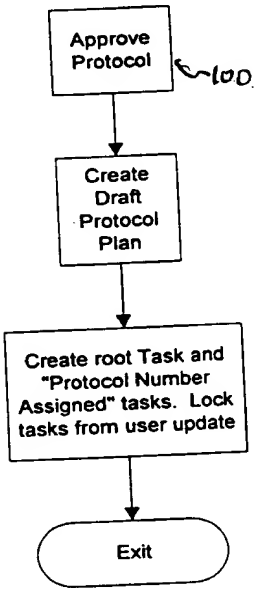


Fig. 27a

PROSIT driven for:

- Protocol Approved

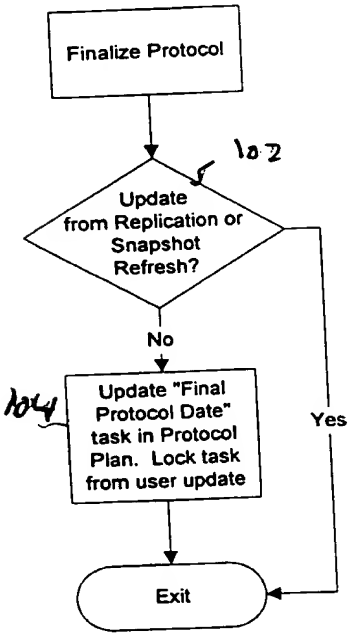


Fig. 27b

6556567 - 960900

Module: Event Manager

PROSIT driven for:

- Initiated/1st Site Initiated & Site Initiated

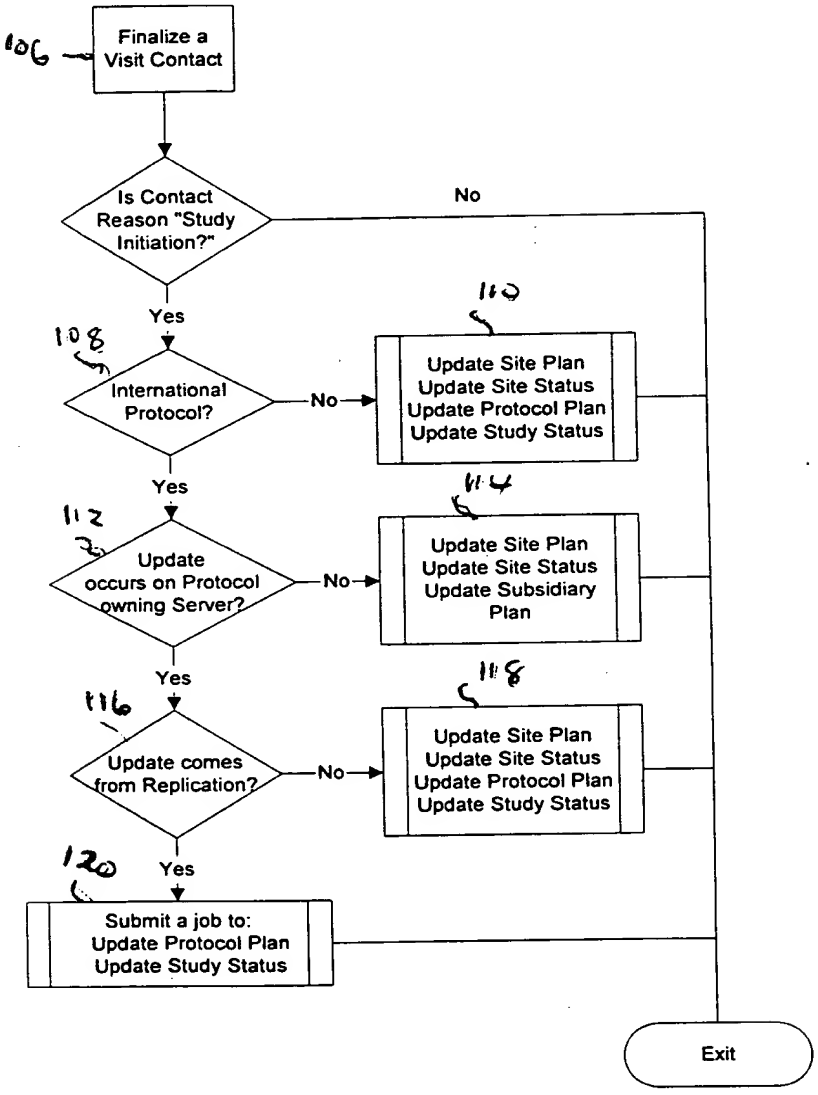


Fig. 27c

0055555.0055555

Module: Event Manager

Milestone (site level) driven for:

- Initiated/1st Site Initiated & Site Initiated
- Screening Ongoing/First Subject, First Visit
- Enrollment Ongoing/First Subject Enrolled

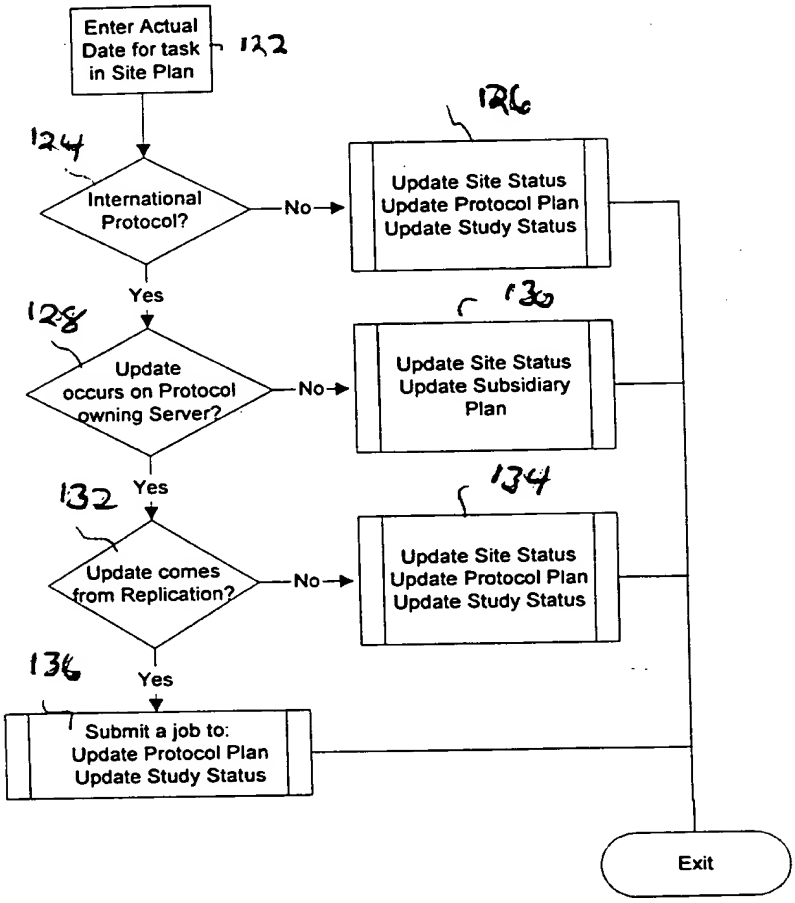


FIG. 27

0050507.0050507

Module: Event Manager

PROSIT and Milestone driven for:

- Last Site Initiated (to Date)

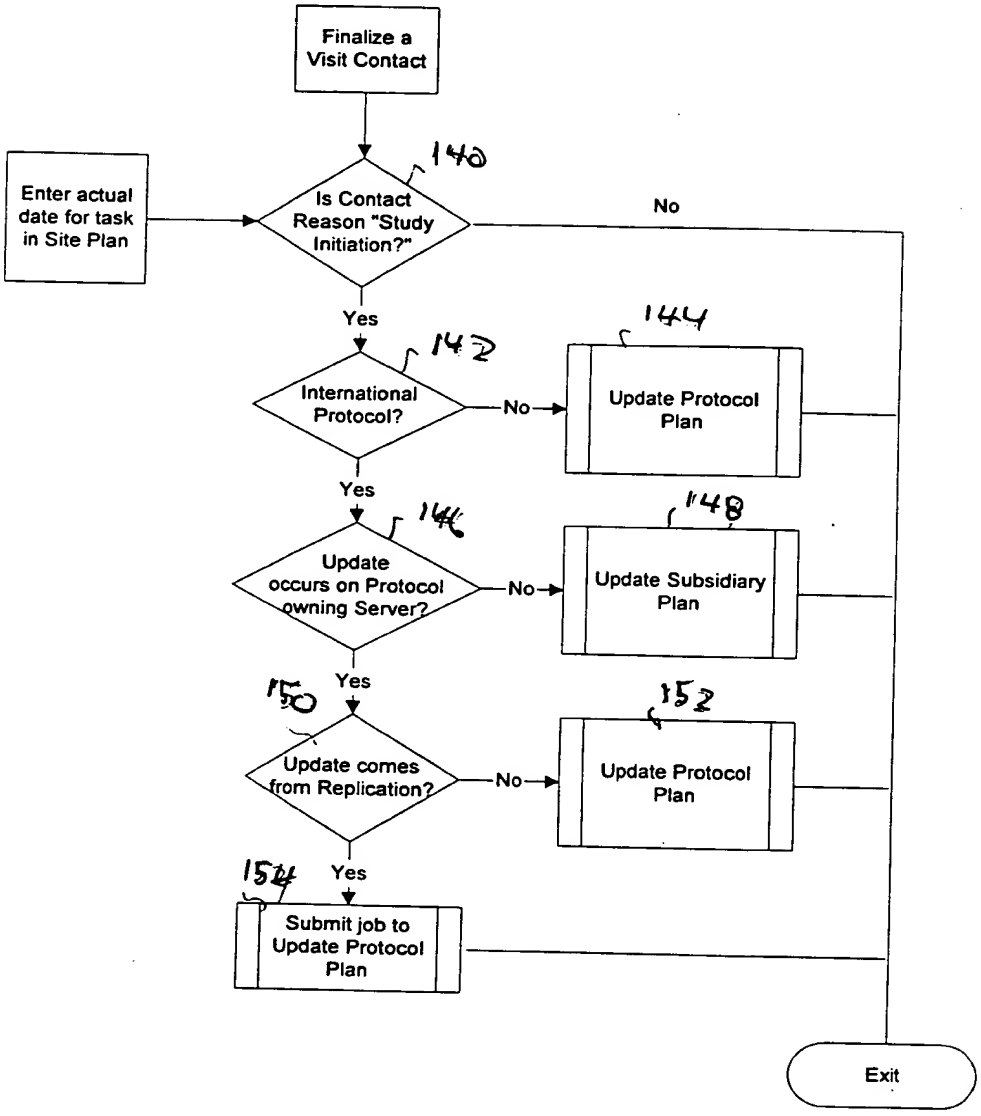


Fig. 27e

09505505.050502

Module: Event Manager

PROSIT driven for:

- Screening Ongoing/First Subject, First Visit

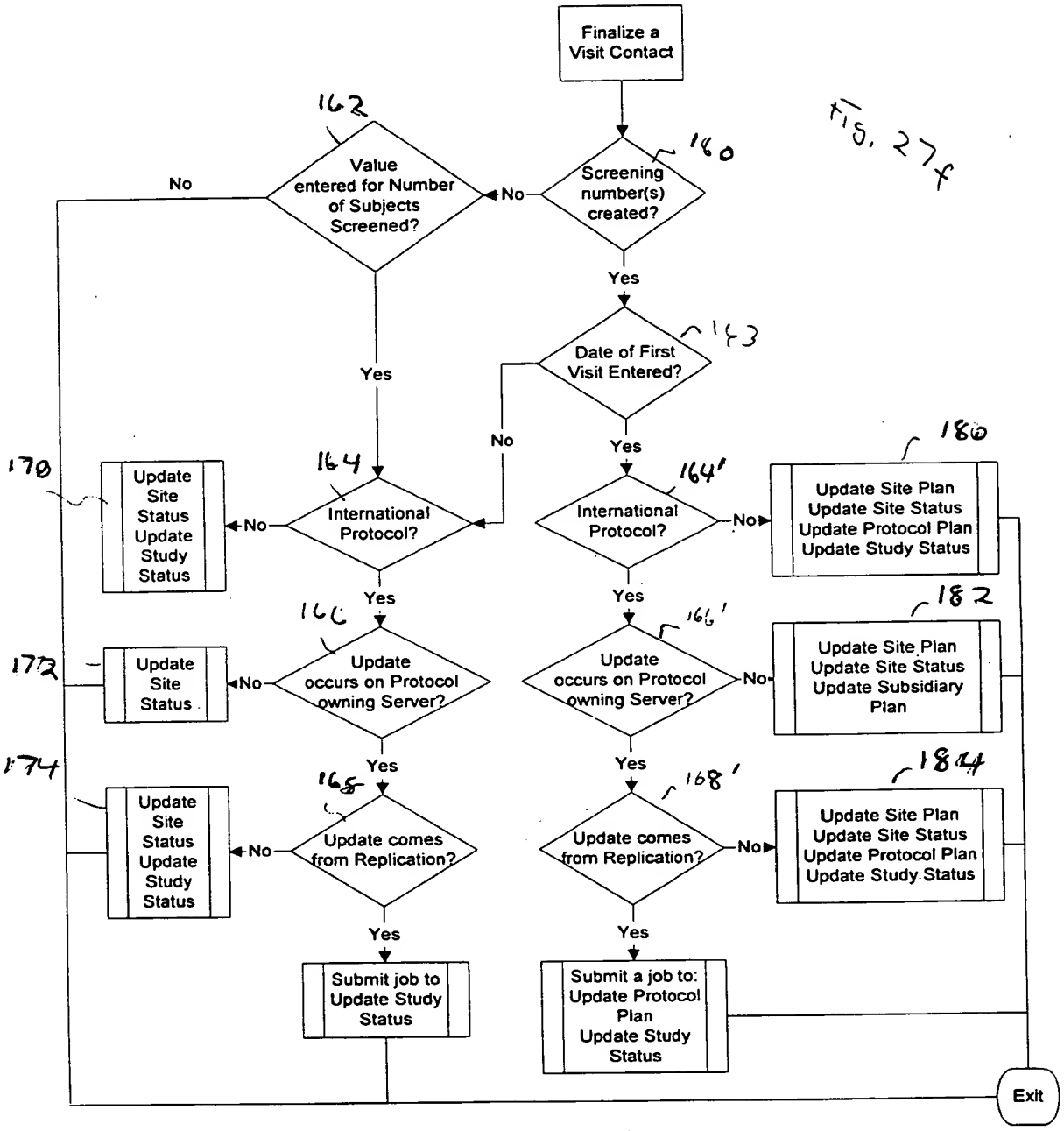


FIG. 27f

Module: Event Manager

PROSIT driven for:

- Enrollment Ongoing/First Subject Enrolled

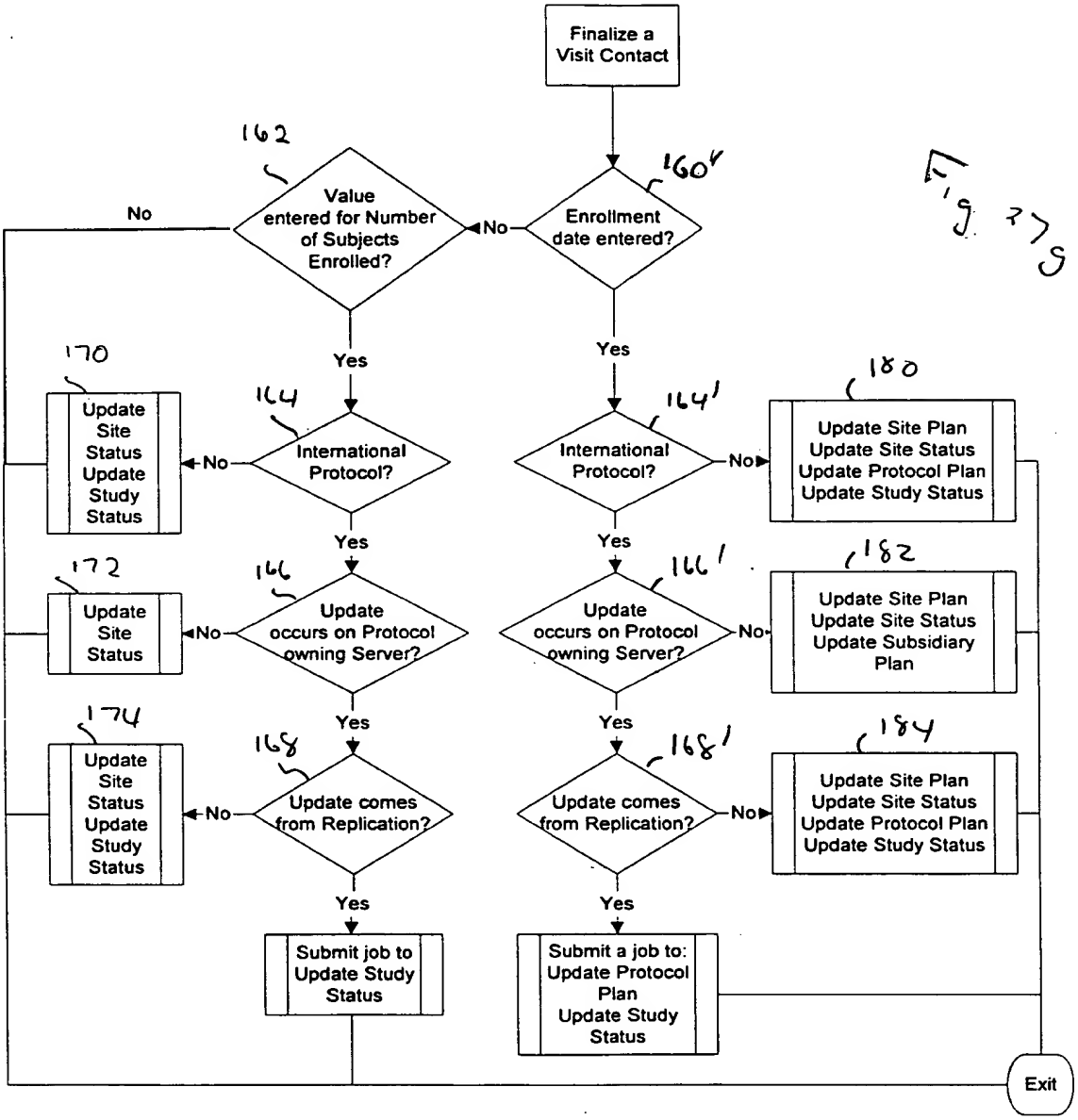


Fig 3

05050-05050

Milestone (site level) driven for:

- Enrollment Complete
- Clinically Complete
- Site Closed

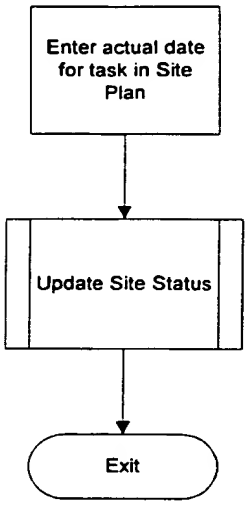
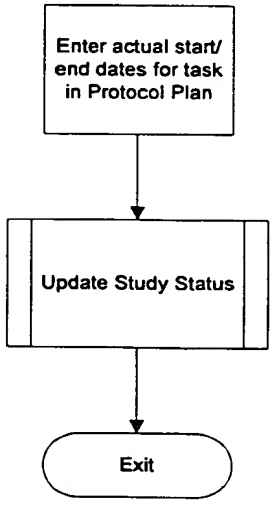


Fig. 27h

Milestone (protocol level) driven for:

- Initiated/1st Site Initiated & Site Initiated
- Screening Ongoing/First Subject, First Visit
- Enrollment Ongoing/First Subject Enrolled
- Enrollment Complete
- Clinically Complete
- All Data In-House
- Data Cleanup Complete
- Database Locked
- CSR Approved

Fig. 27i



0505N-0000

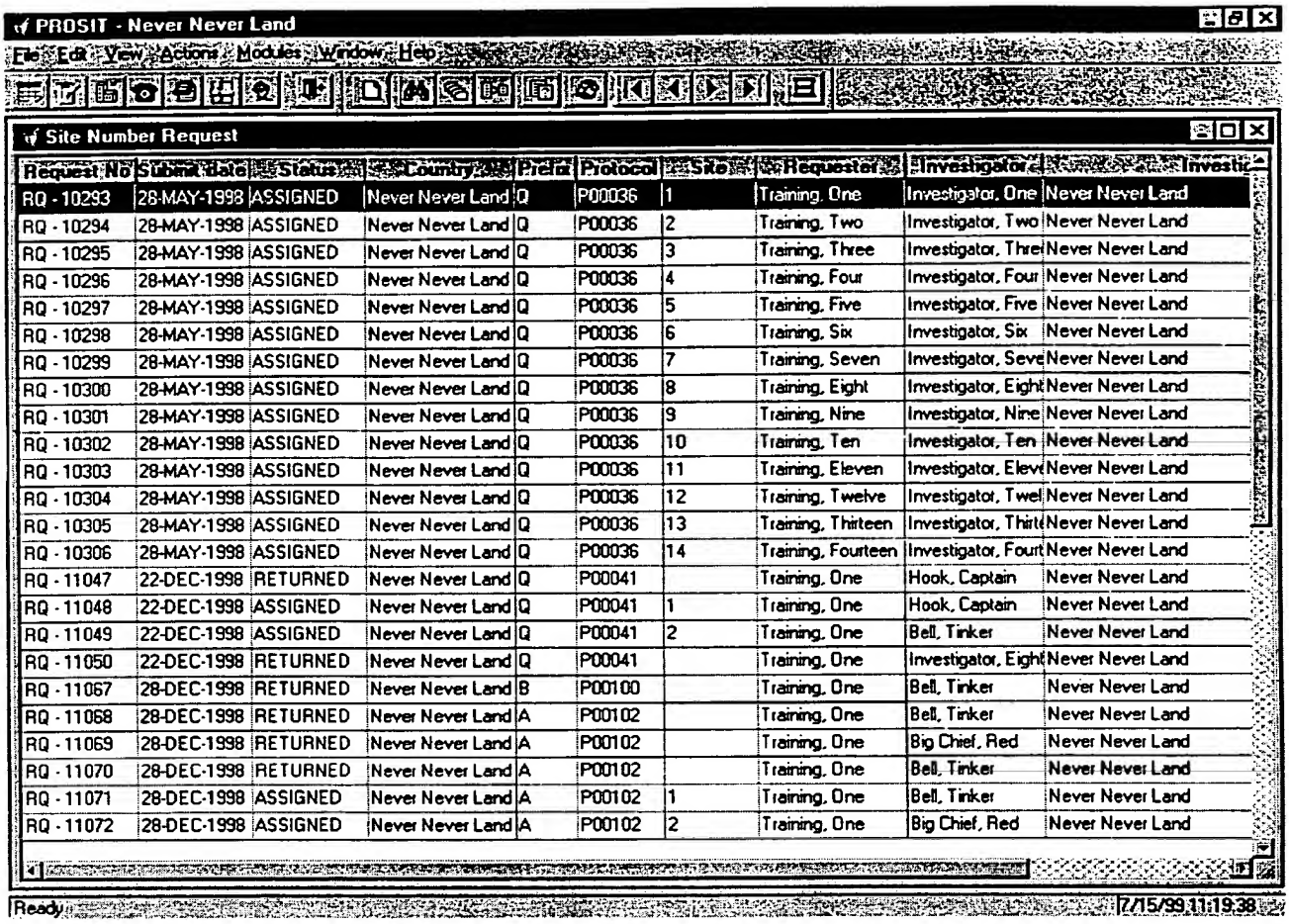
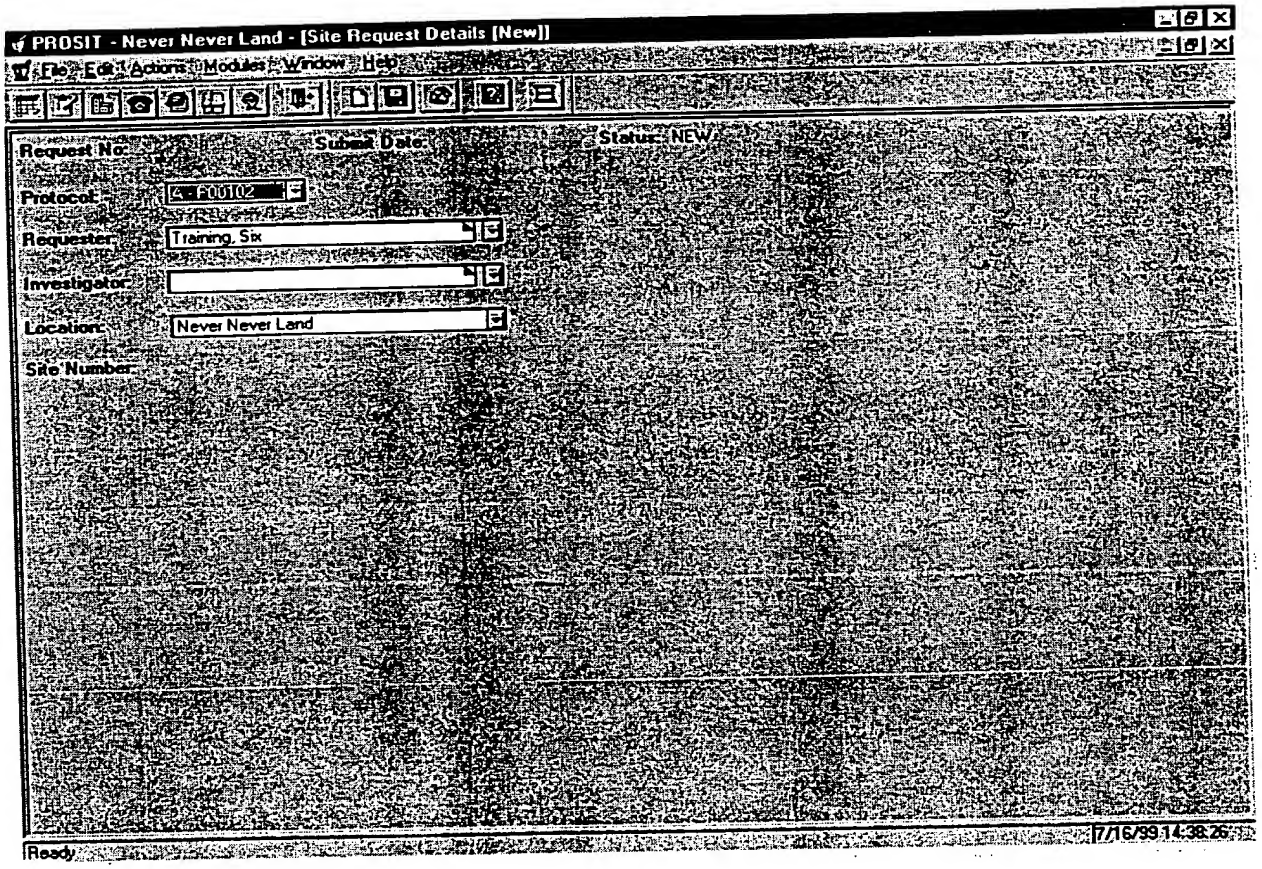


Fig. 28

09506,2999

Fig. 29



0955567.0600

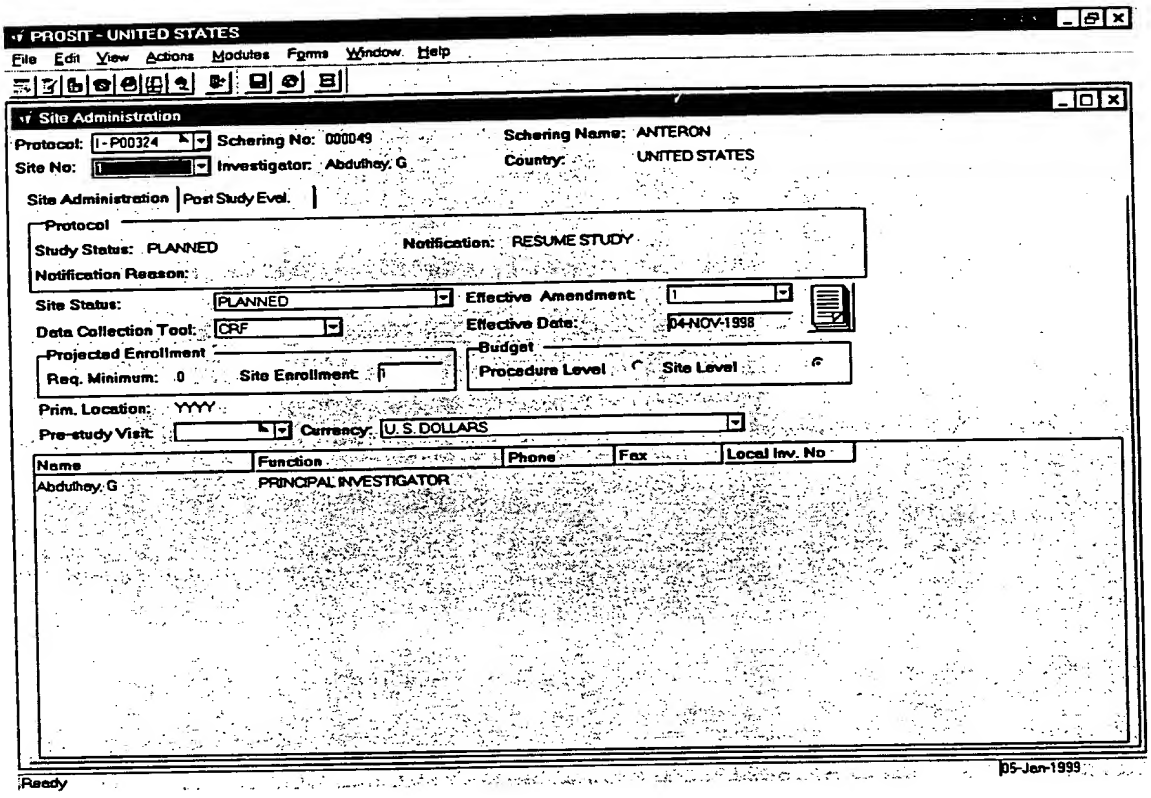

PROSIT - UNITED STATES
File Edit View Actions Modules Forms Window Help
Site Administration
Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON
Site No: 1 Investigator: Abduthey, G Country: UNITED STATES
Site Administration | Post Study Eval.
Protocol
Study Status: PLANNED Notification: RESUME STUDY
Notification Reason:
Site Status: PLANNED Effective Amendment: 1
Data Collection Tool: CRF Effective Date: 04-NOV-1998
Projected Enrollment
Req. Minimum: 0 Site Enrollment: 1
Budget
Procedure Level Site Level
Prim. Location: YYYY
Pre-study Visit: Currency: U.S. DOLLARS
Name Function Phone Fax Local Inv. No
Abduthey, G PRINCIPAL INVESTIGATOR
Ready
05-Jan-1999

Fig. 30

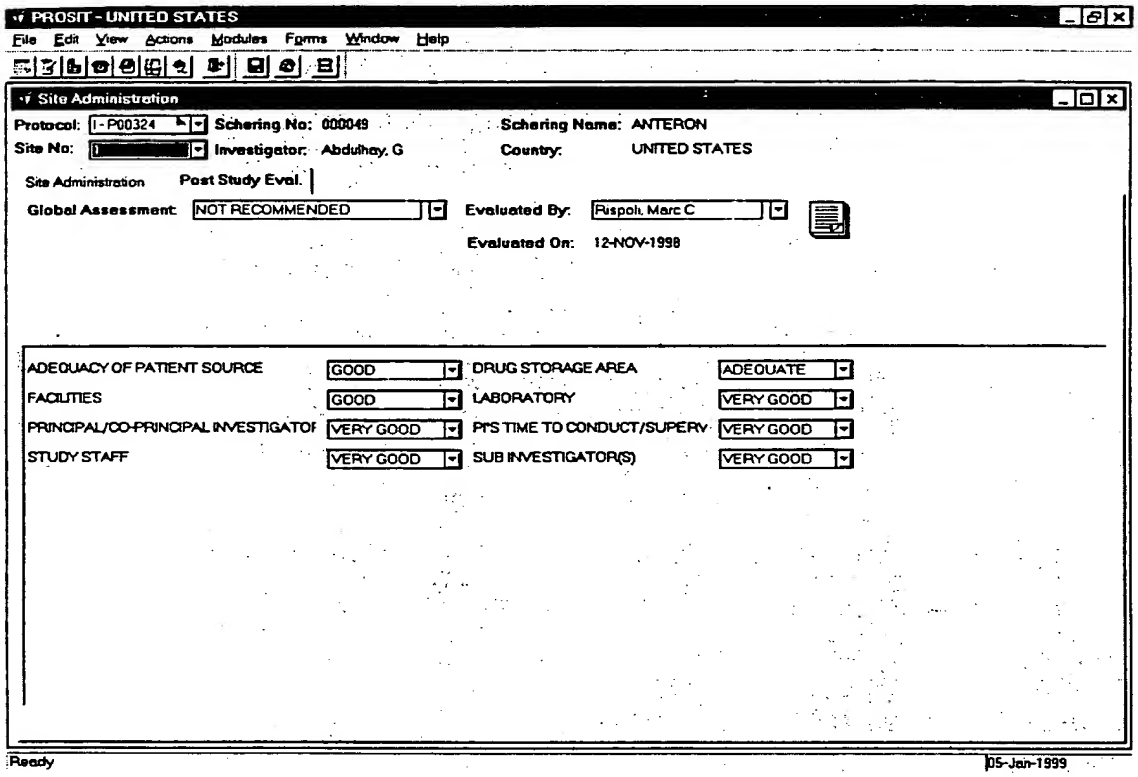


Fig. 31

Confidential

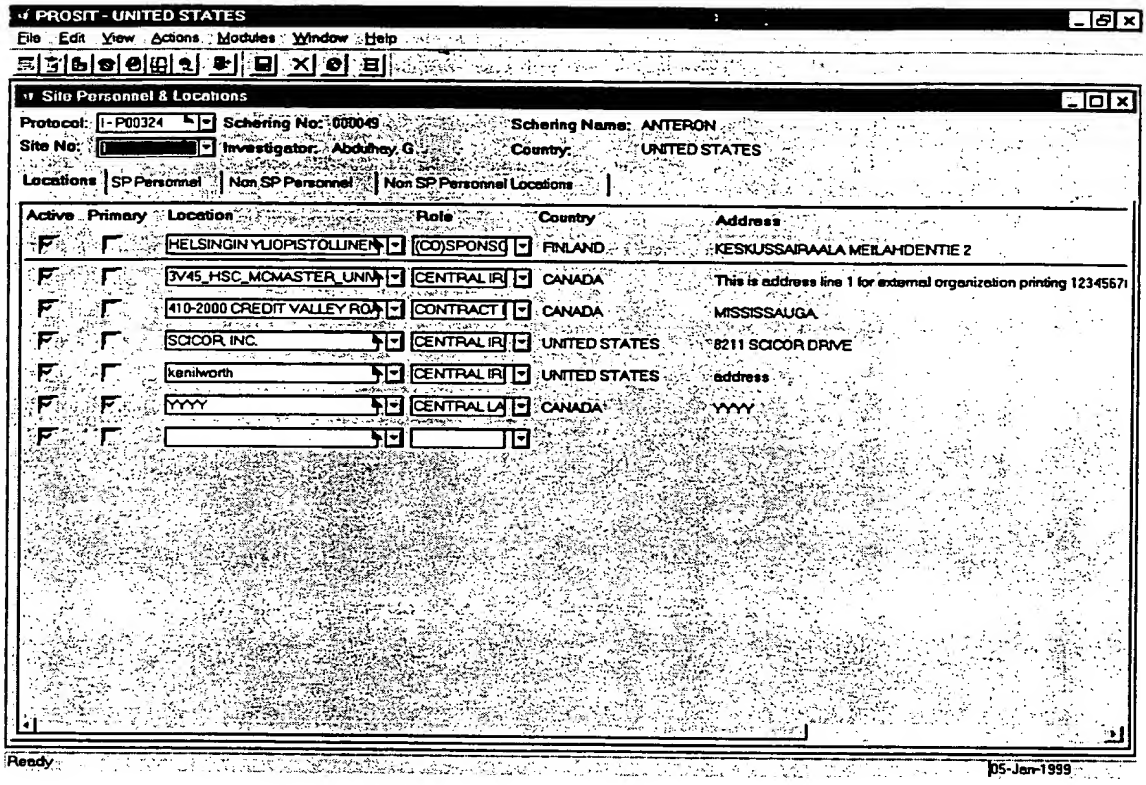


Fig. 32

0090650

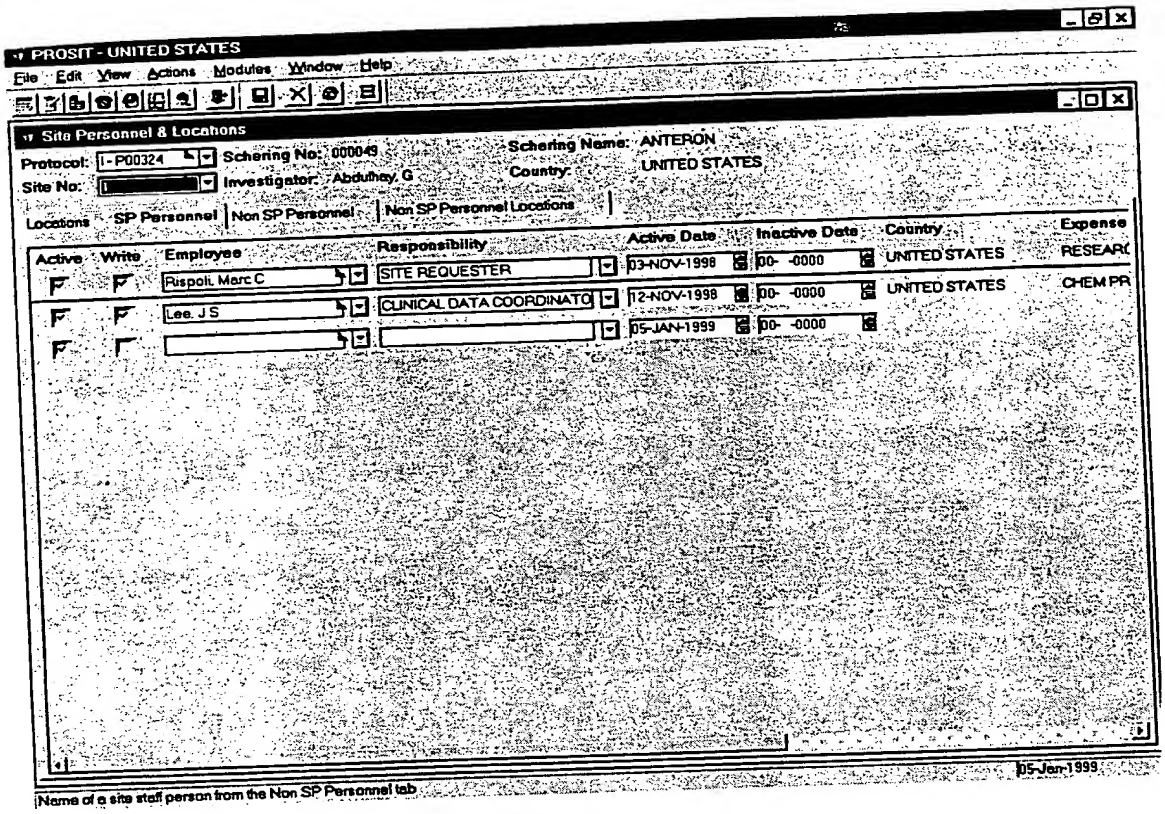
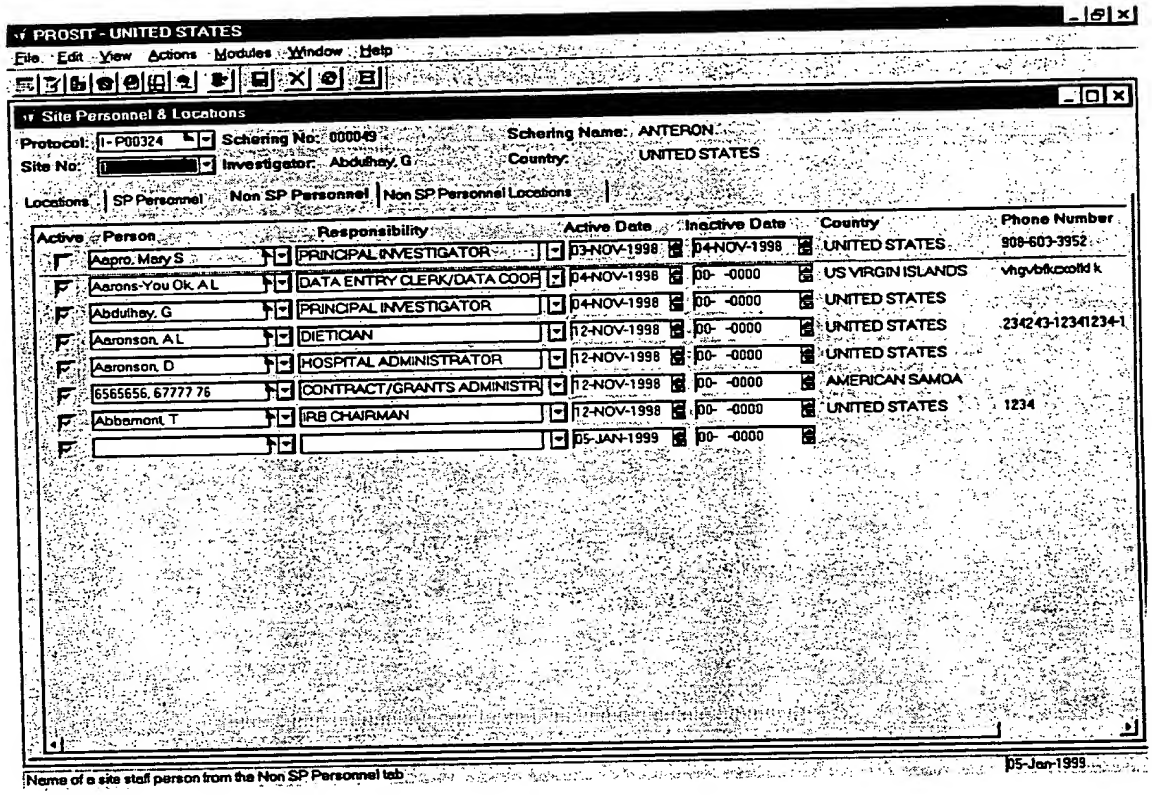


Fig. 33

0955557.0900



Fig, 34

0055550 · 0055550

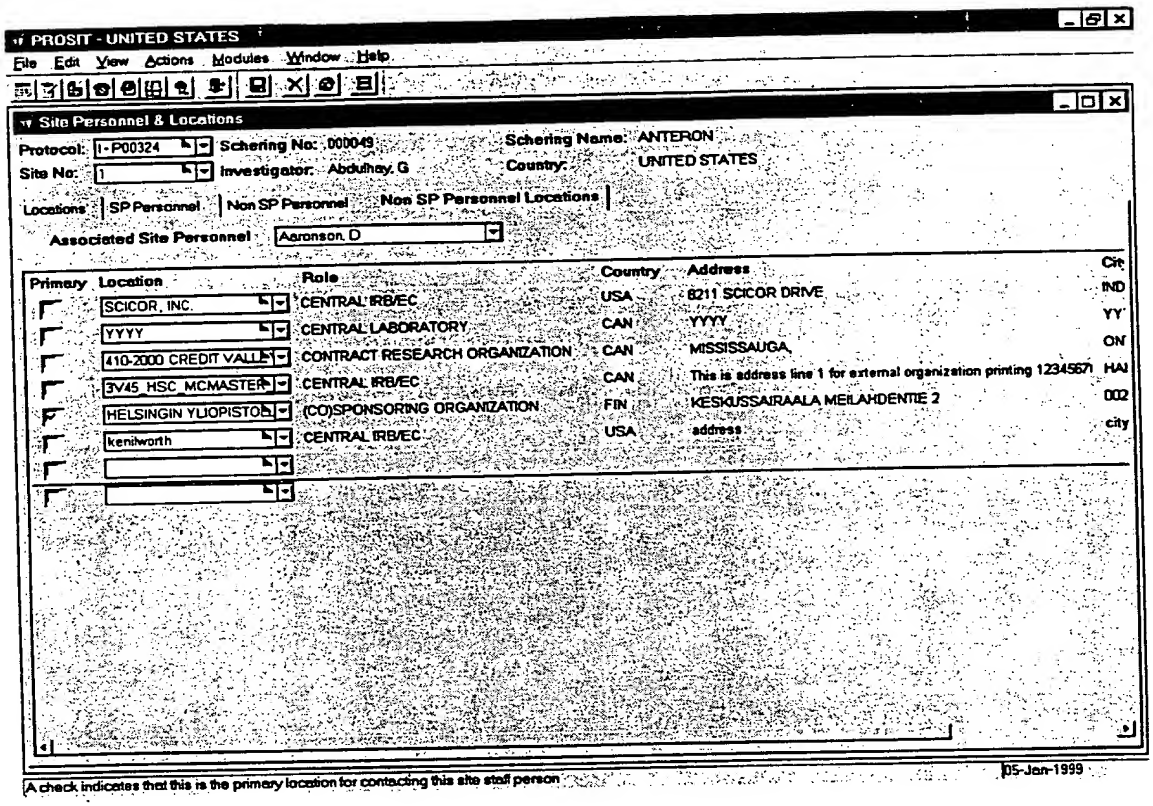


Fig. 35

0055557.0606

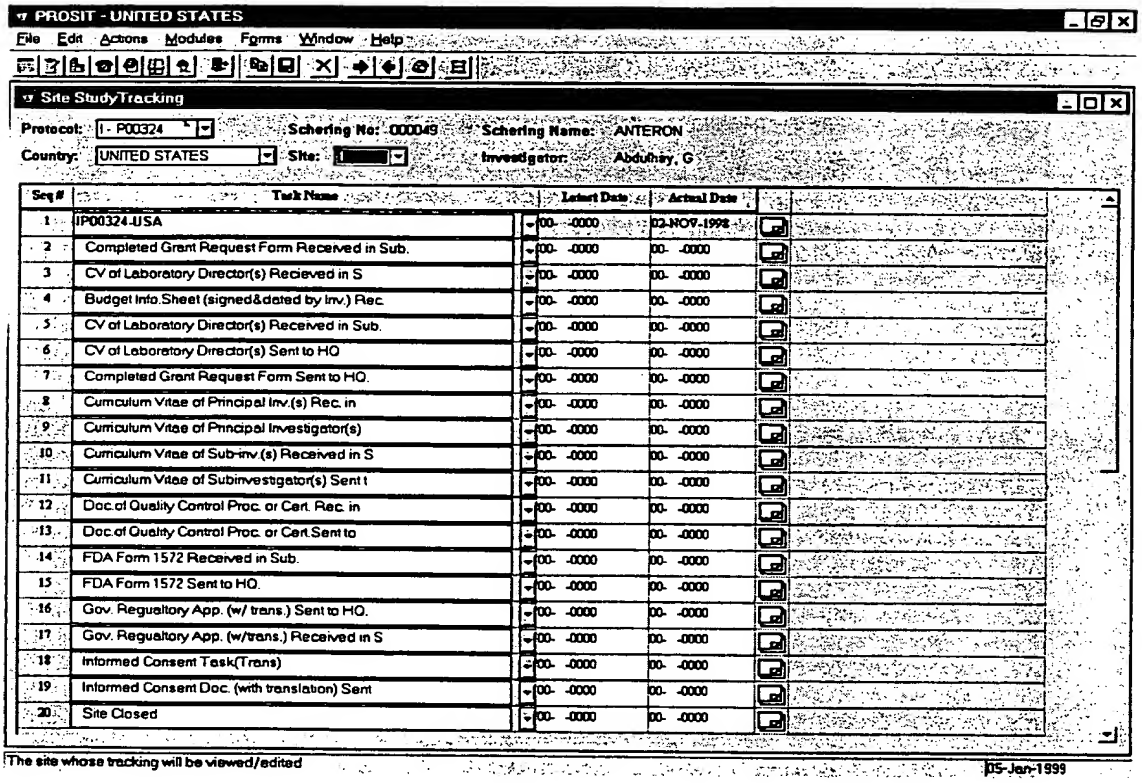


FIG. 36

0050/0050

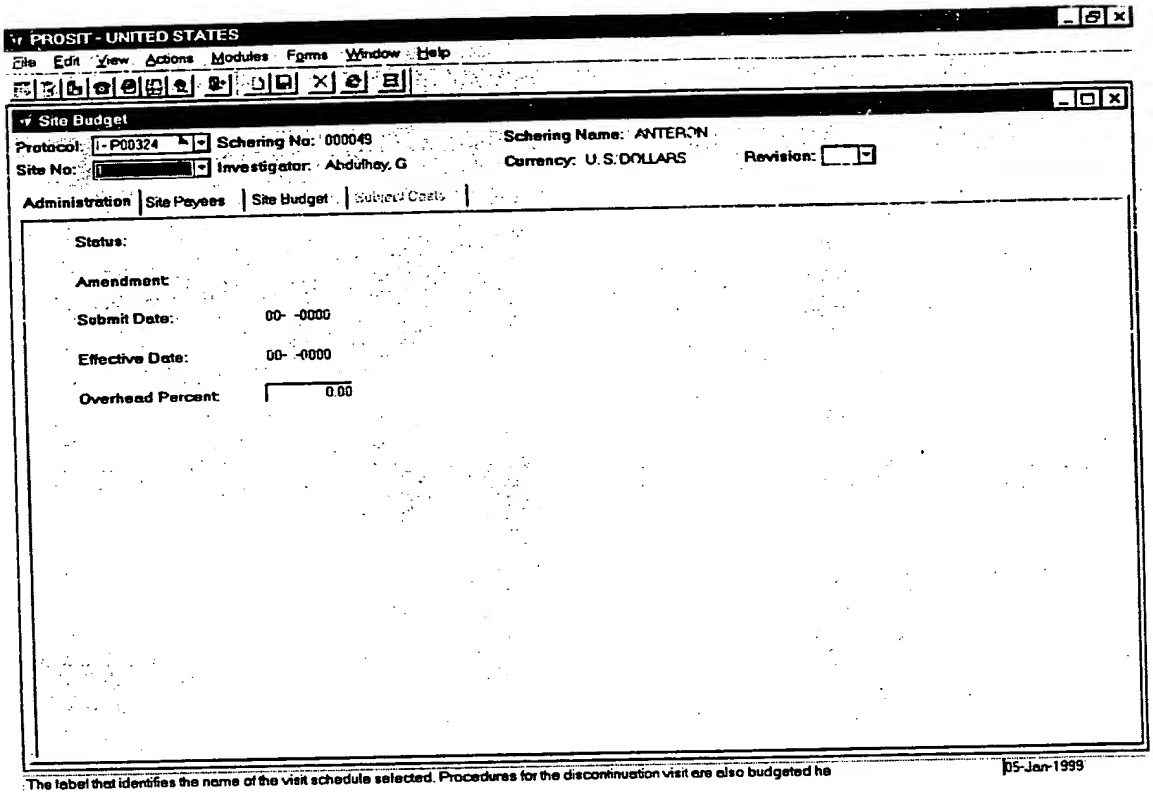


Fig. 37

0955969 : 0955969

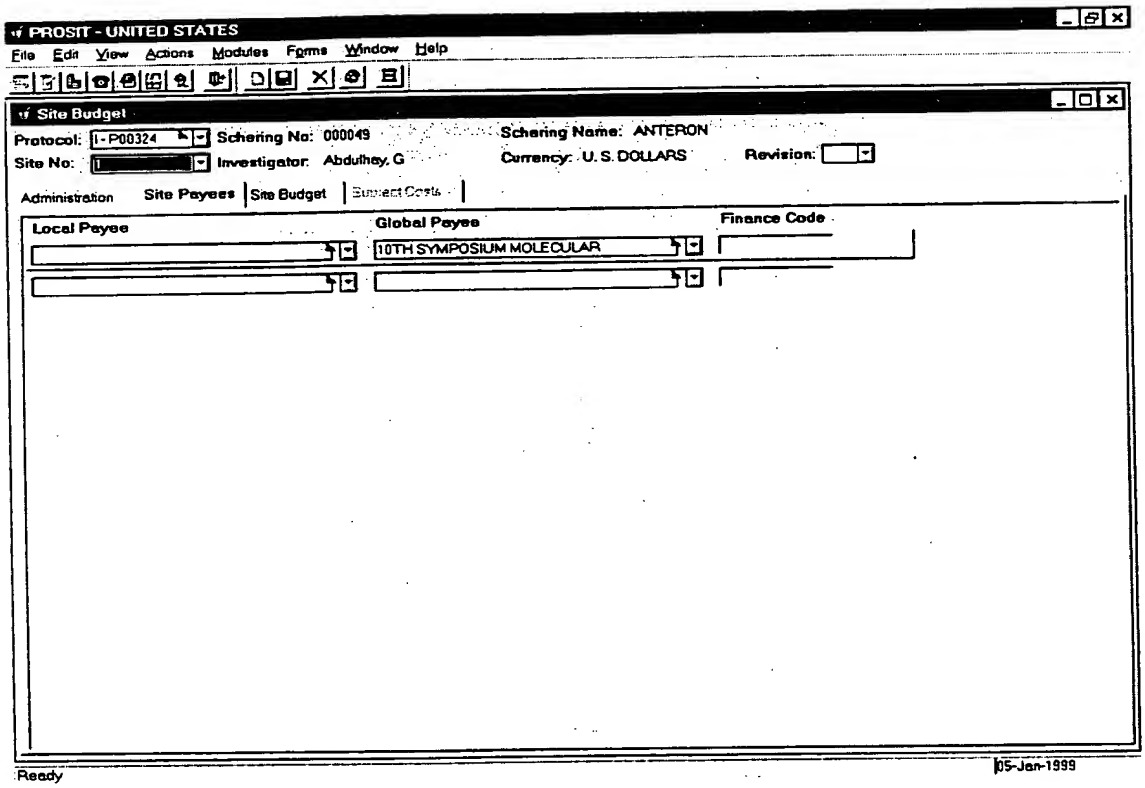


Fig. 38

0050507.0050507

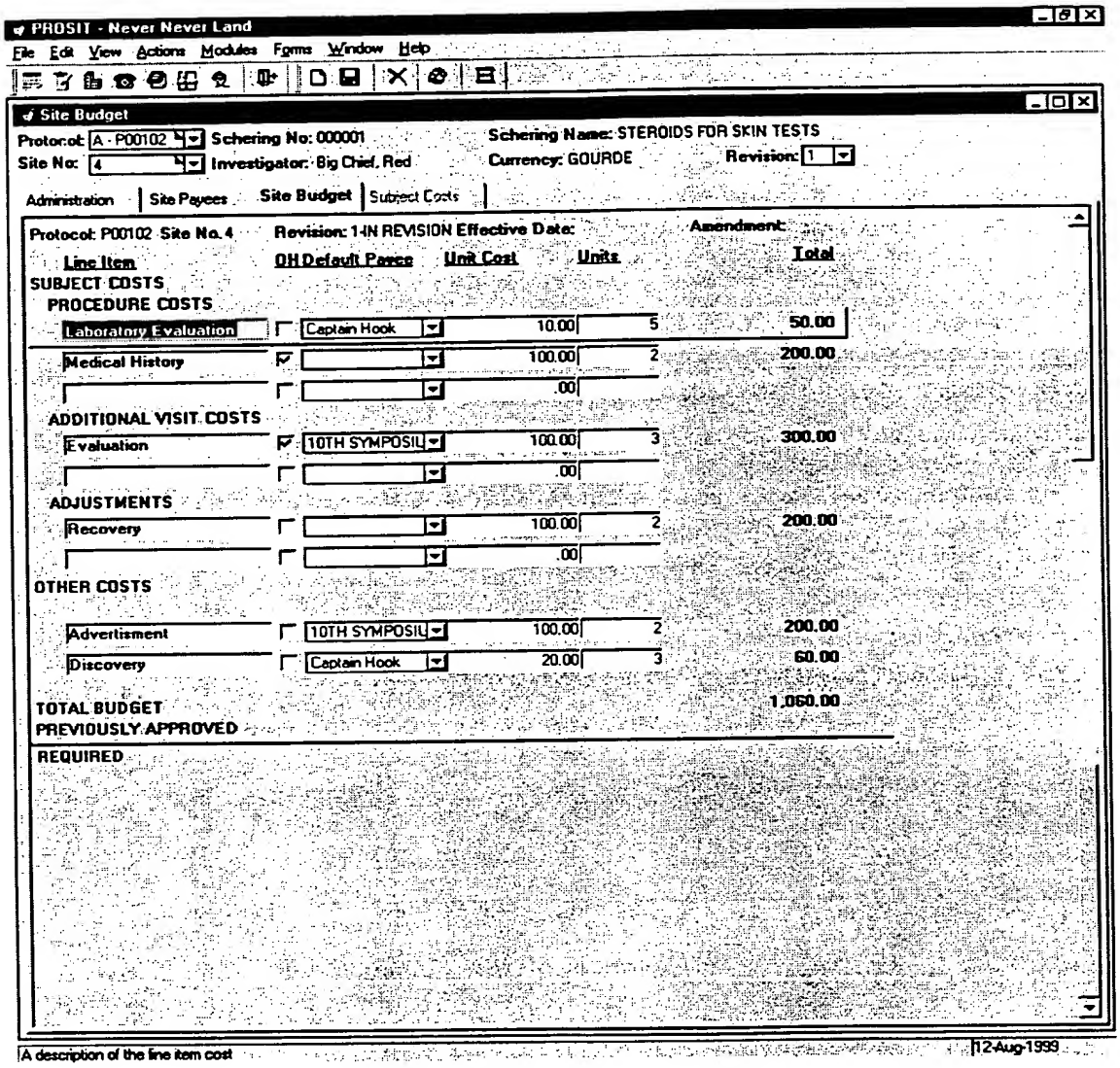


Fig. 39

0005350/2

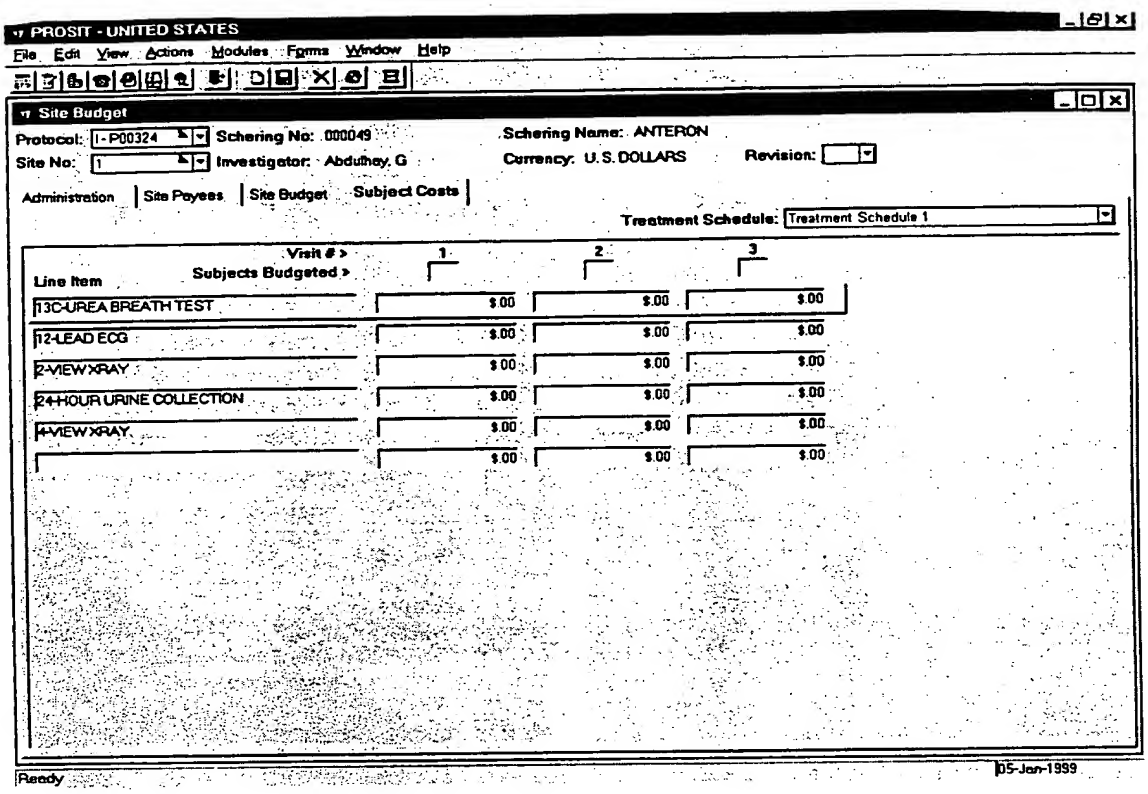


Fig. 40

0056596

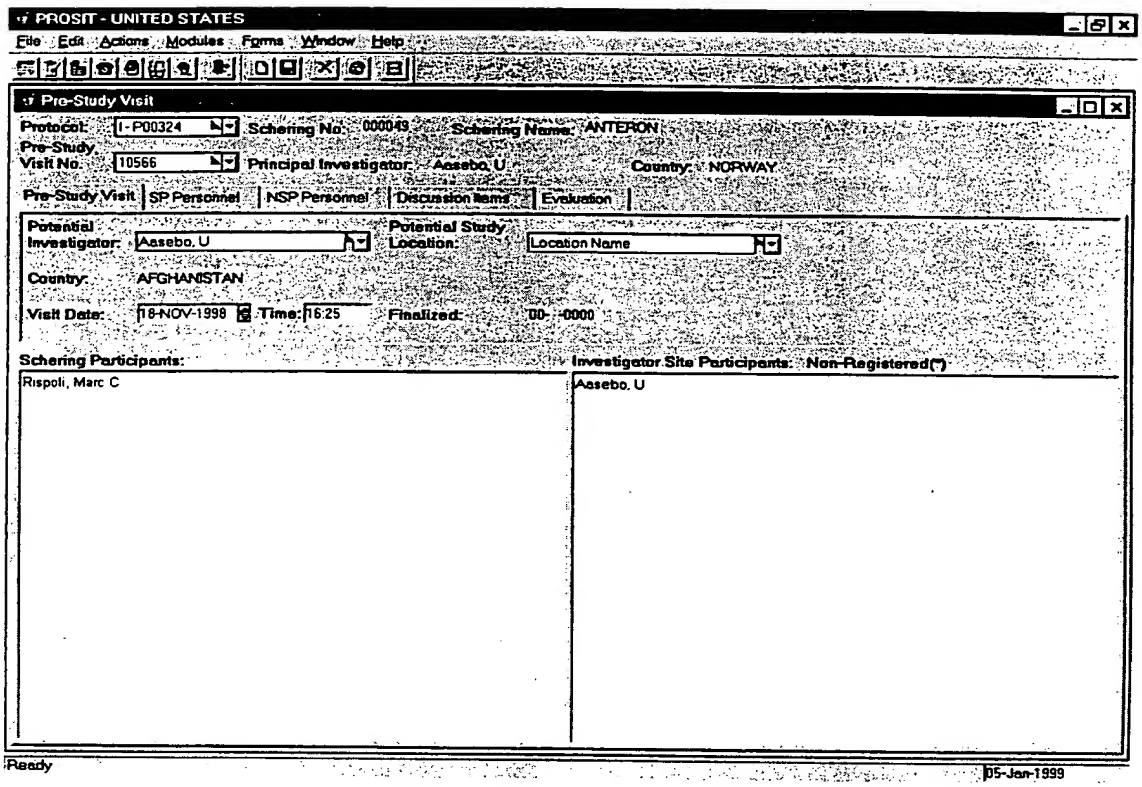


Fig. 41

0055555 - 0055600

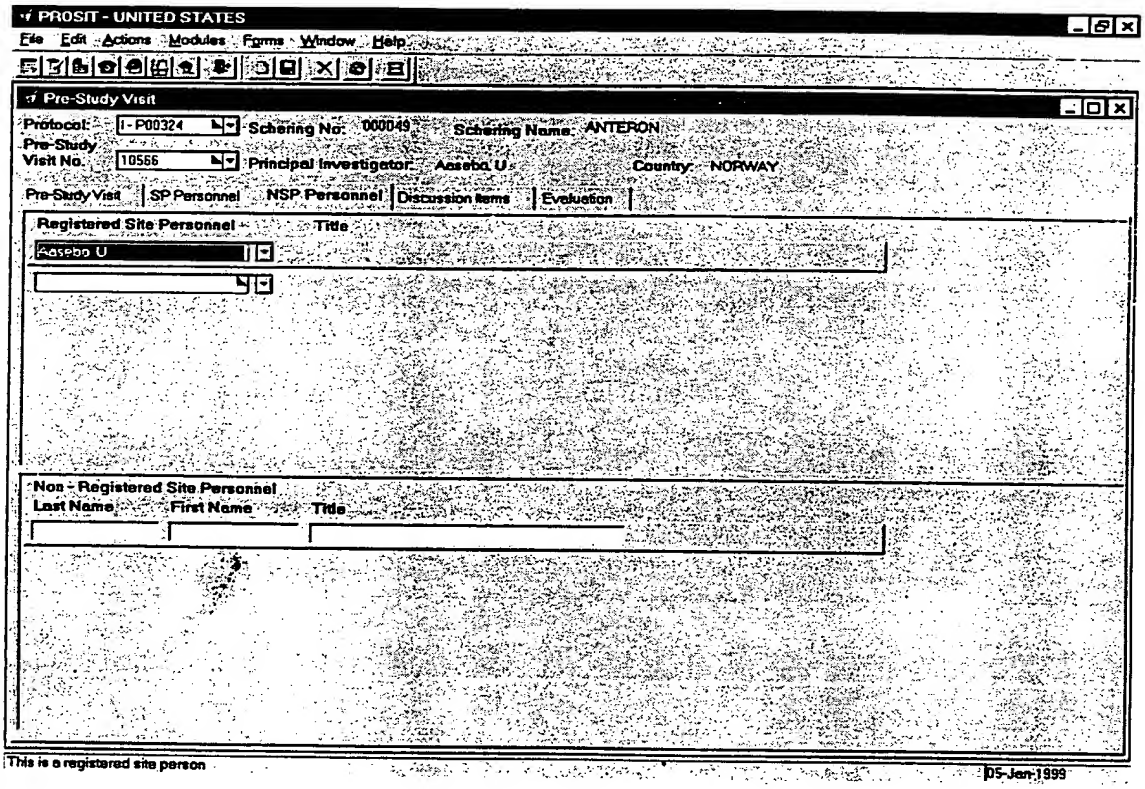


Fig. 42

0950950 · 0950950

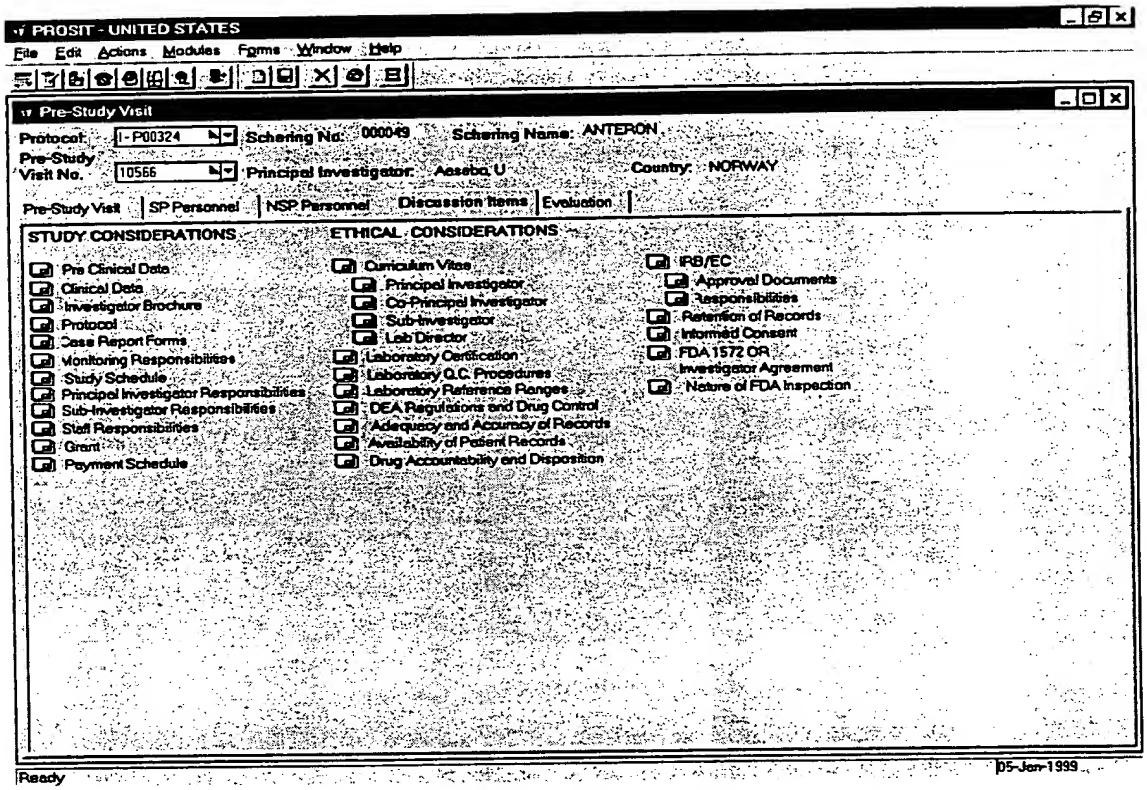


Fig. 43

0955597 0900600

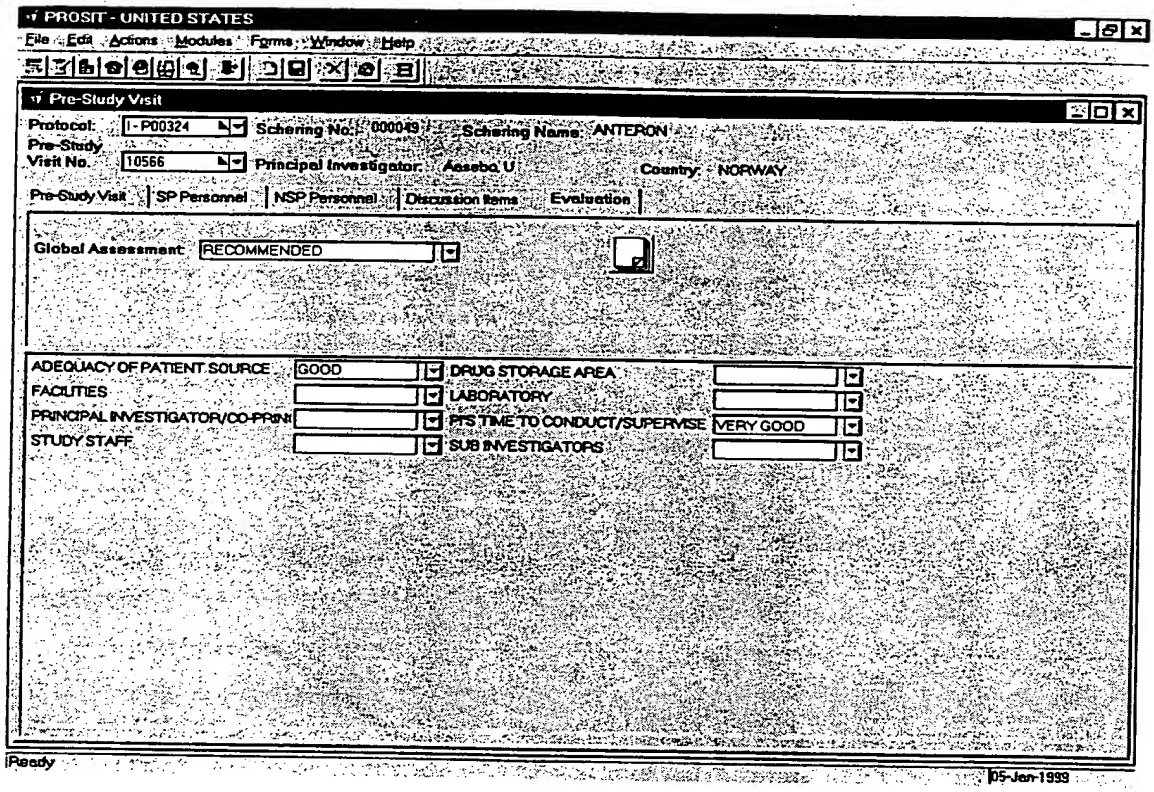


Fig. 44

0055-0000

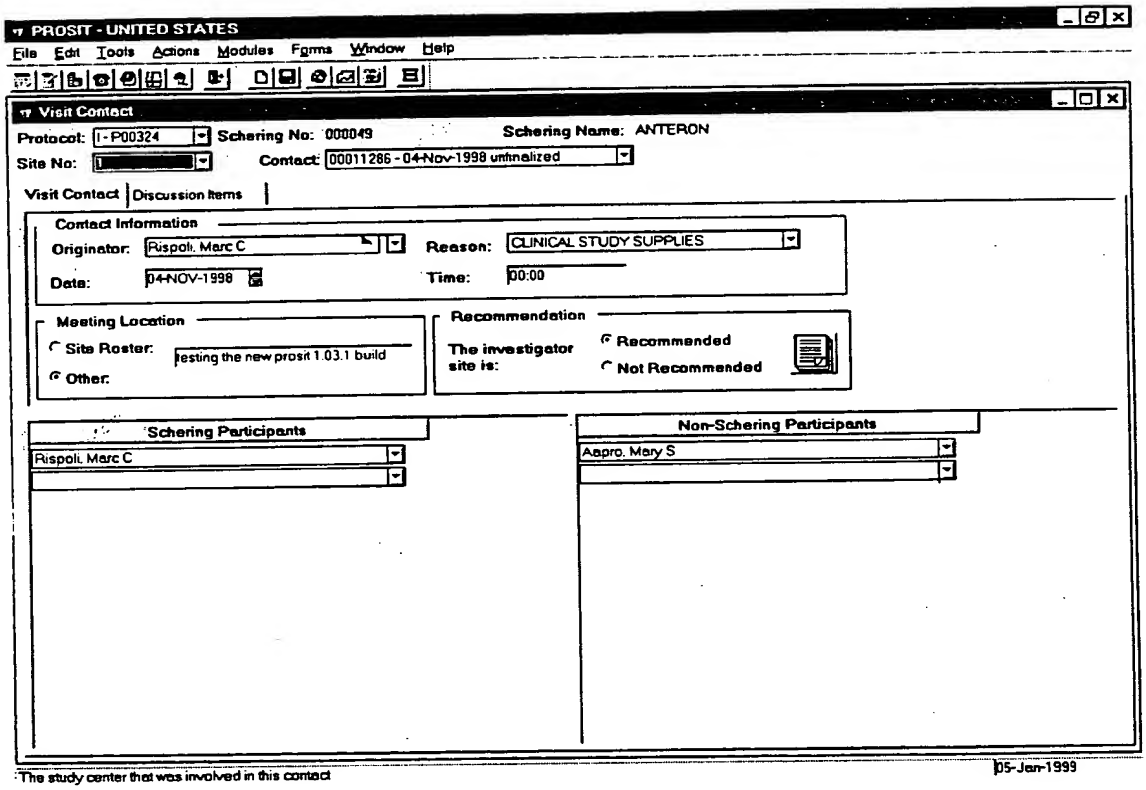


Fig. 45

0055505v1 050505

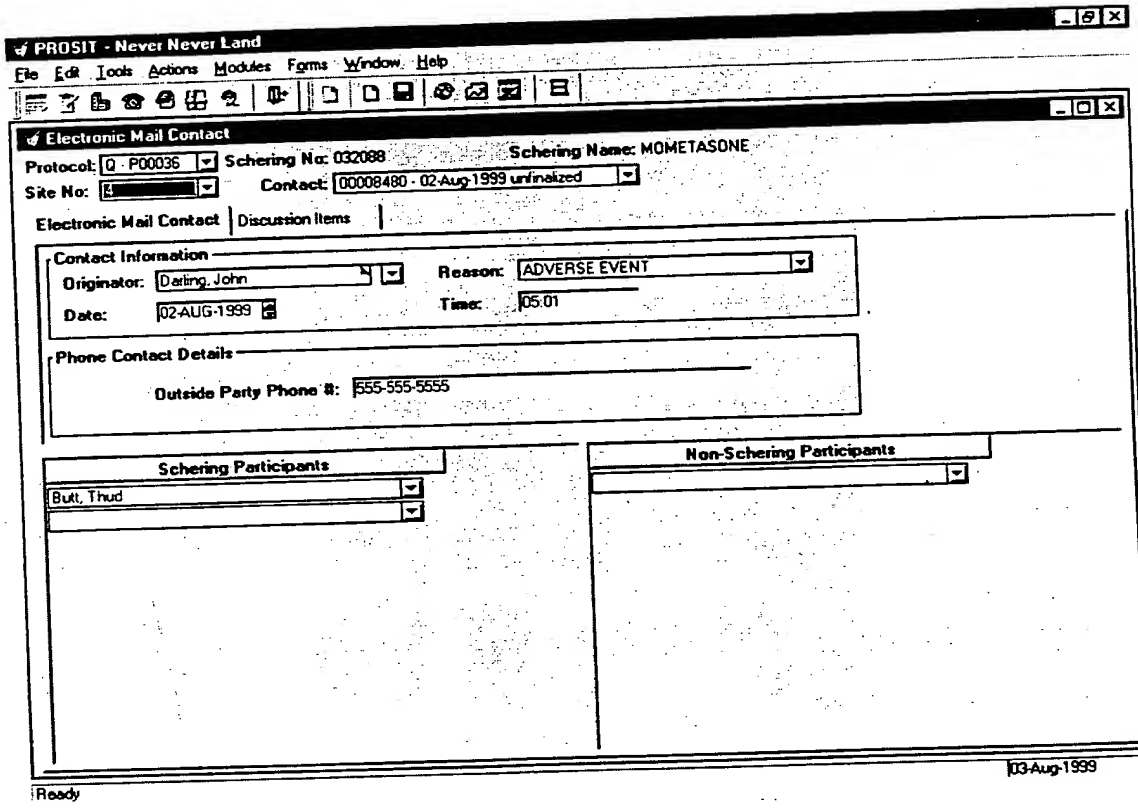


Fig. 46

5555555555

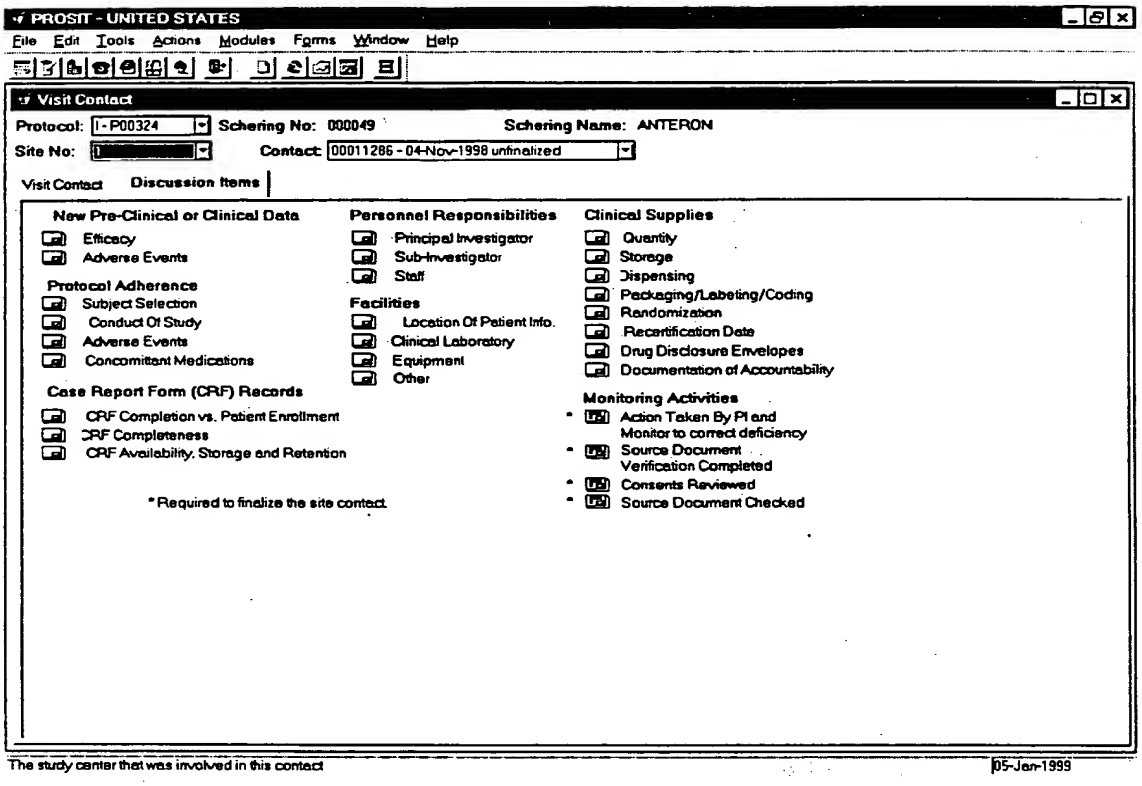


Fig. 47

0955959.0000

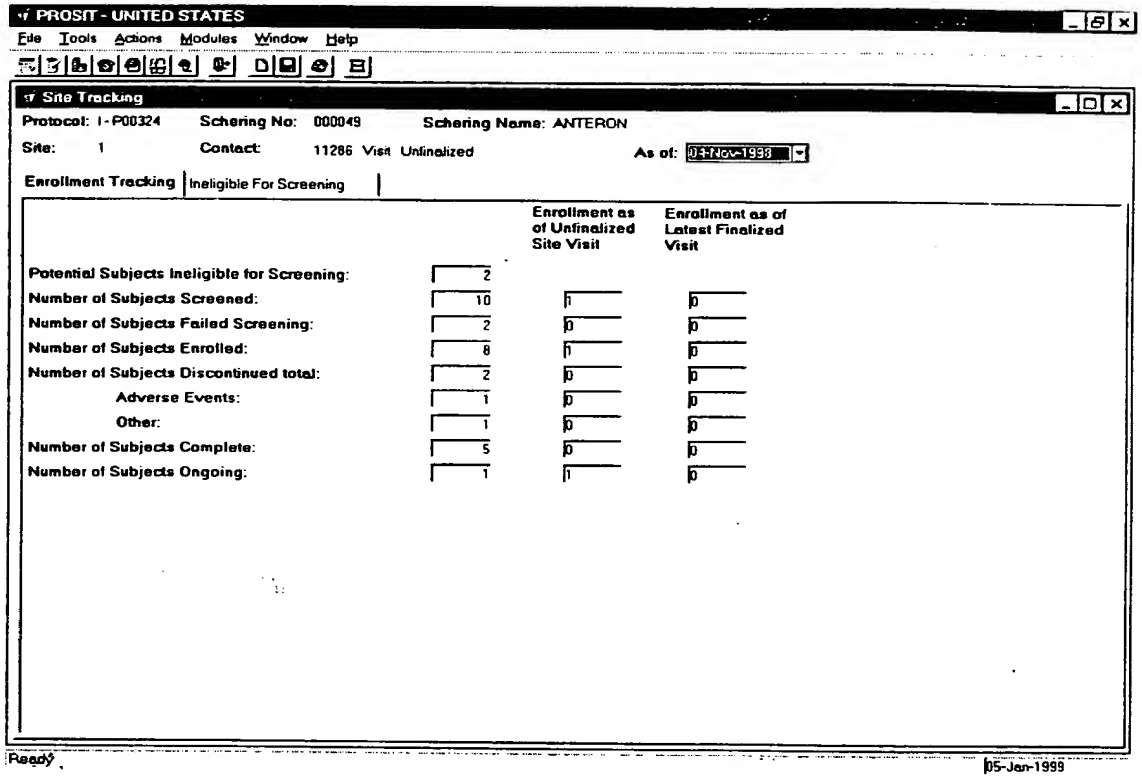


Fig. 48a

SCHERING-PLOUGH 0056

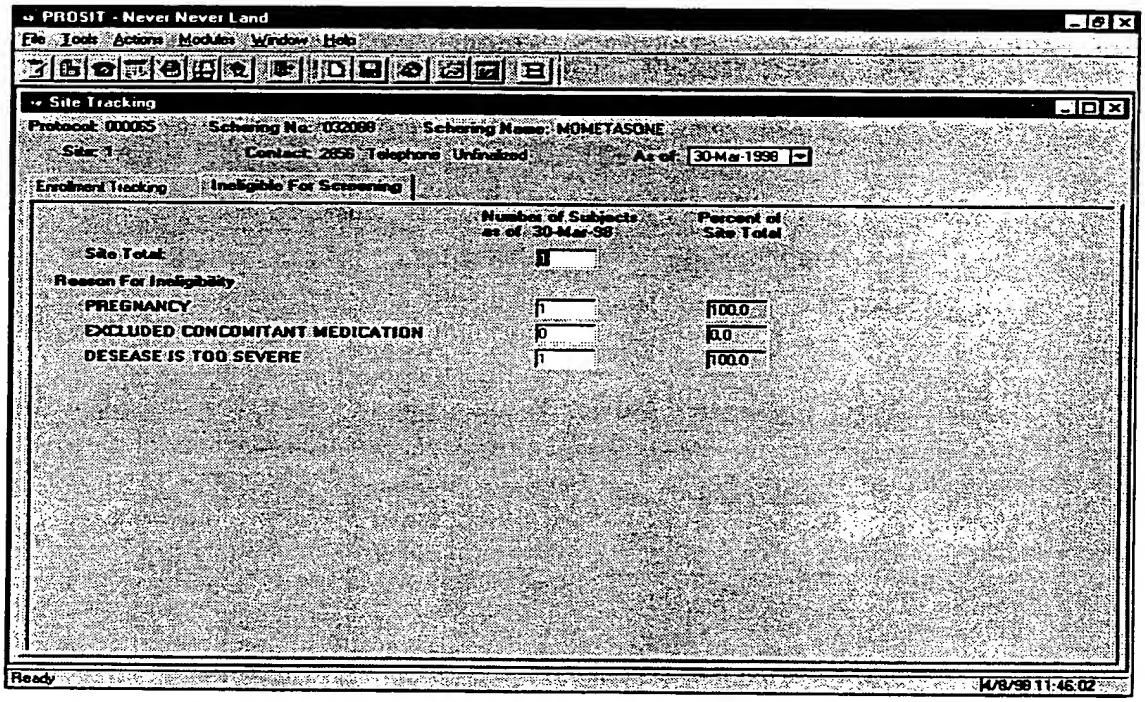


Fig. 48b

0955569 0960900

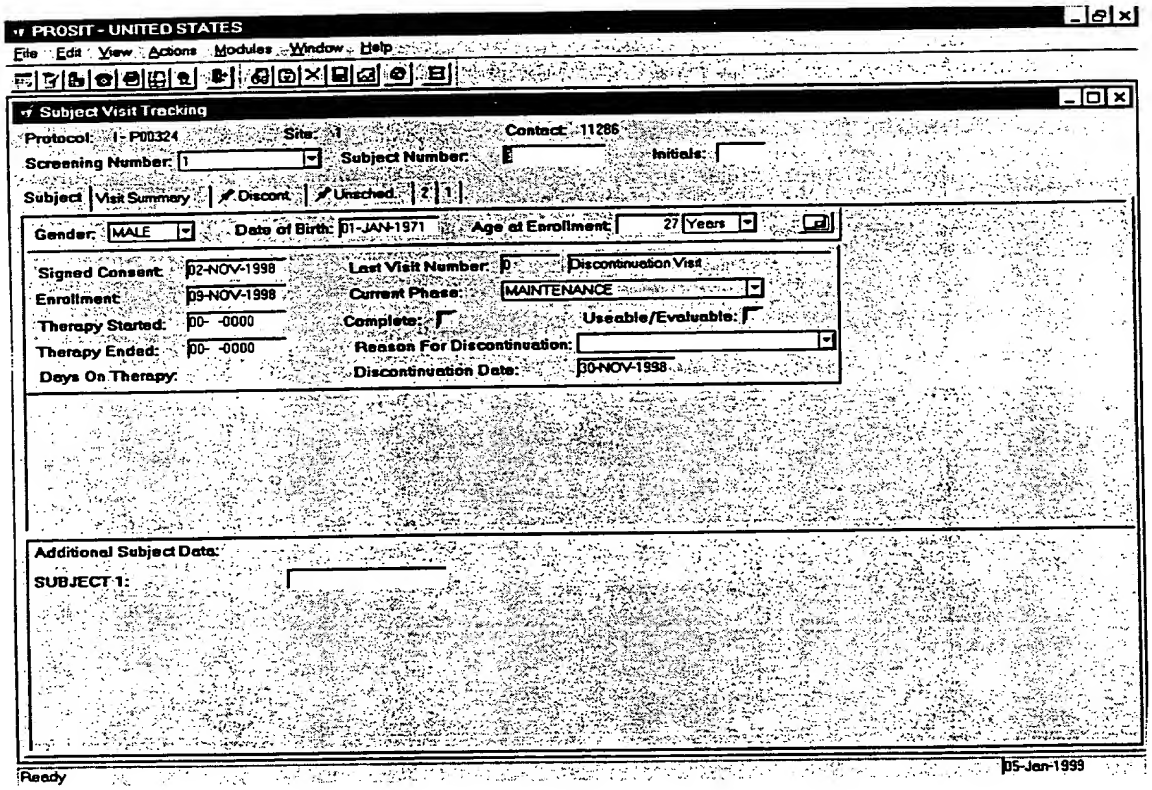


Fig. 49

0055555/0550800

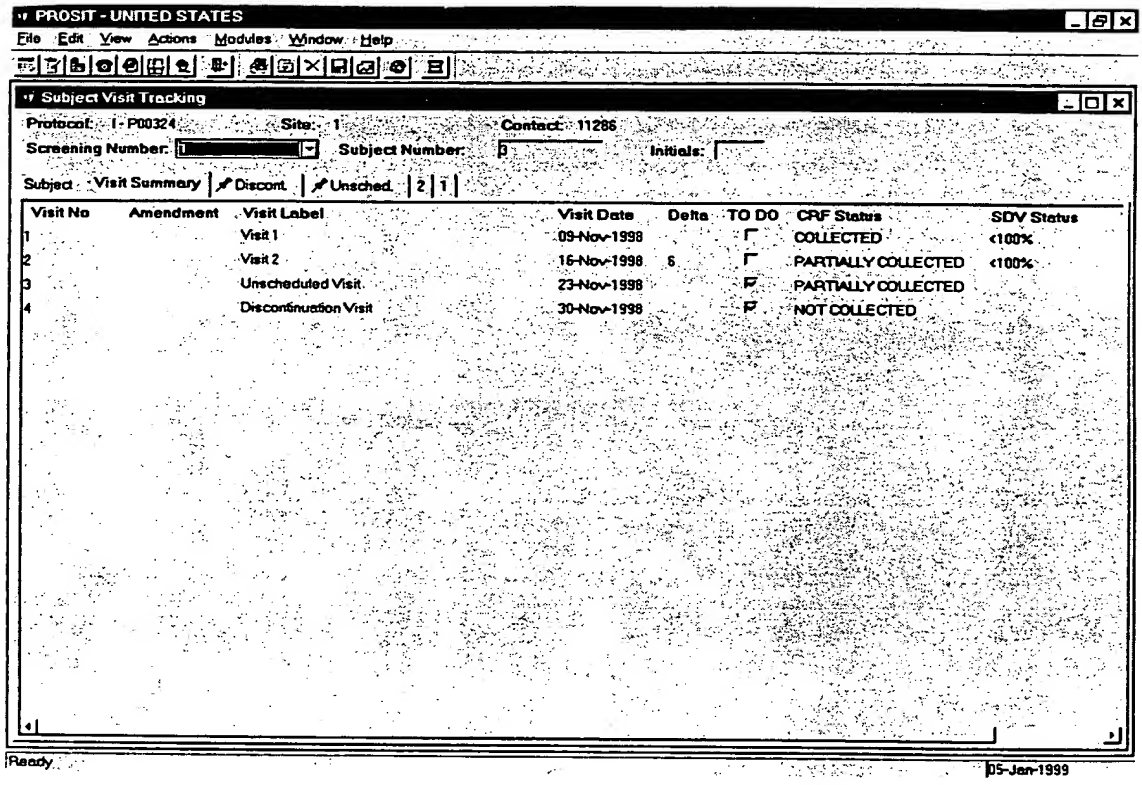


Fig. 5a

09595808 v 09595808

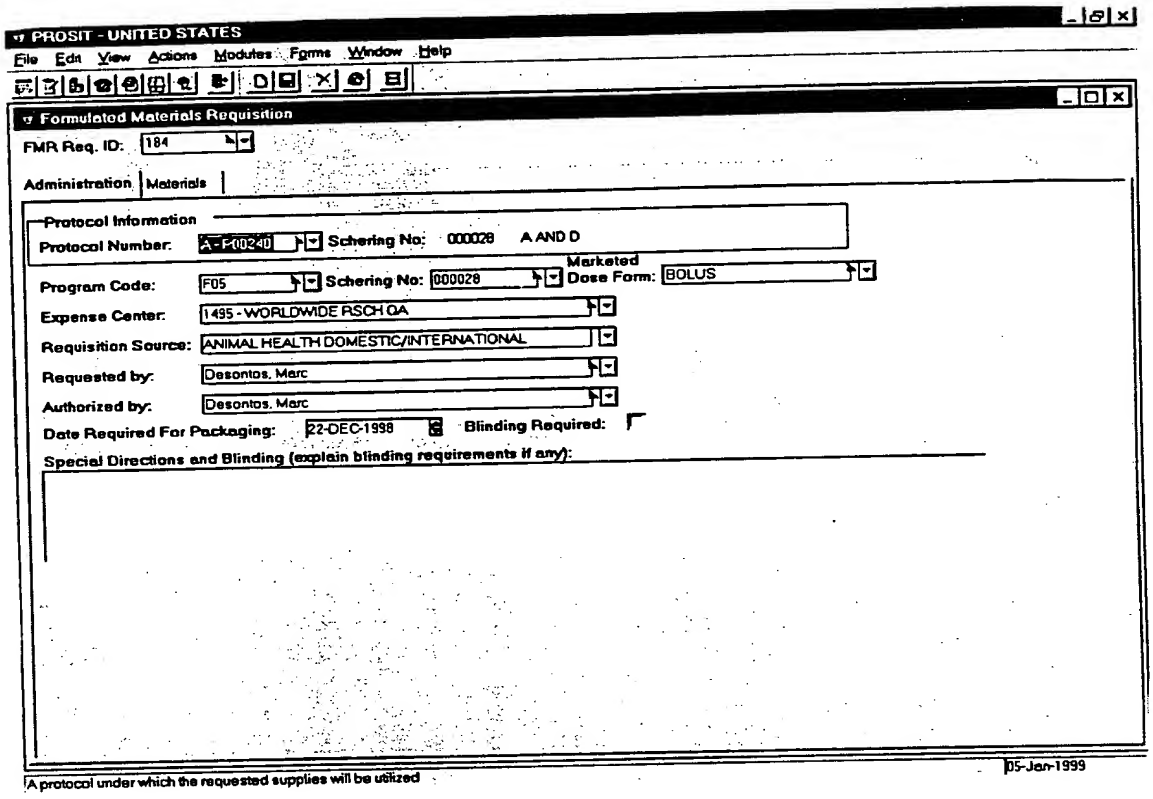


Fig. 51

0055556v5 0055556

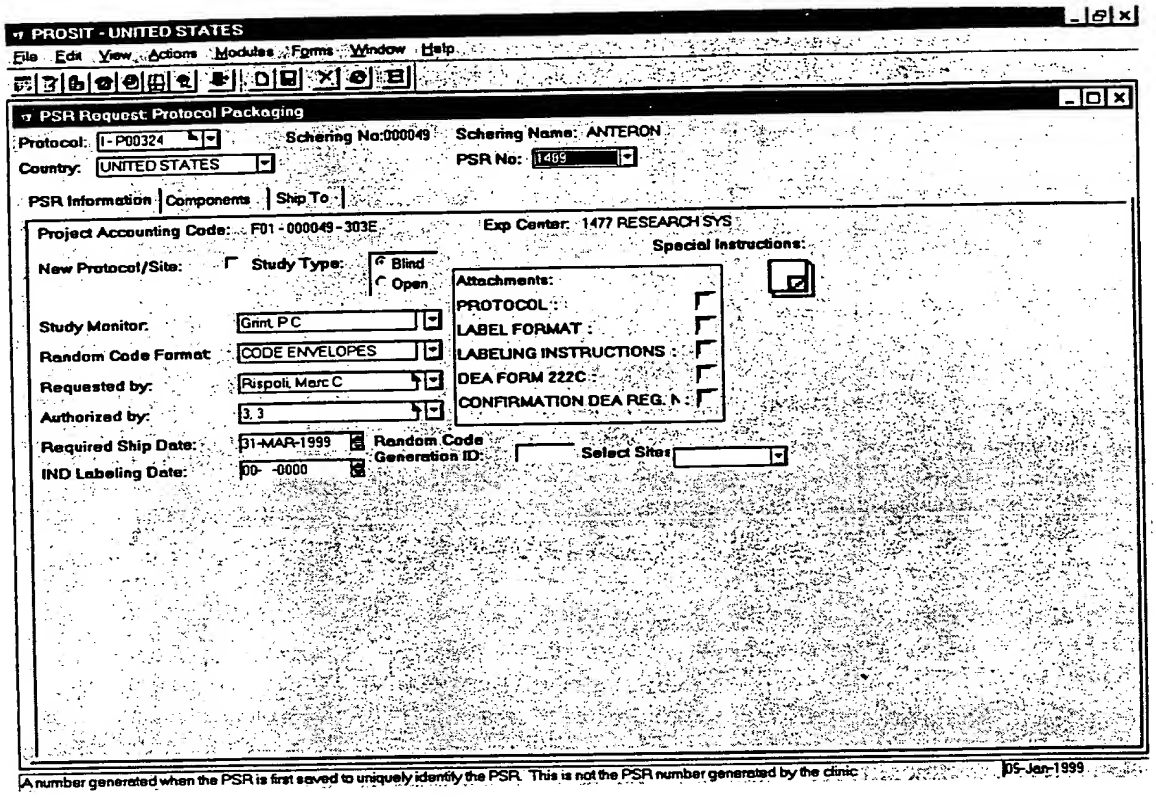

PROSIT - UNITED STATES
File Edit View Actions Modules Forms Window Help
PSR Request: Protocol Packaging
Protocol: I-P00324
Schering No:000049
Schering Name: ANTERON
Country: UNITED STATES
PSR No: 1489
PSR Information
Components
Ship To
Project Accounting Code: F01 - 000049 - 303E
Exp Center: 1477 RESEARCH SYS
Special Instructions:
New Protocol/Site:
Study Type:
Blind
Open
Attachments:
PROTOCOL :
LABEL FORMAT :
LABELING INSTRUCTIONS :
DEA FORM 222C :
CONFIRMATION DEA REG. N :
Study Monitor: Grint, P C
Random Code Format: CODE ENVELOPES
Requested by: Rispoli, Marc C
Authorized by: 3, 3
Required Ship Date: 31-MAR-1999
IND Labeling Date: 00- -0000
Random Code Generation ID:
Select Site:
A number generated when the PSR is first saved to uniquely identify the PSR. This is not the PSR number generated by the clinic
05-Jan-1999

Fig. 52

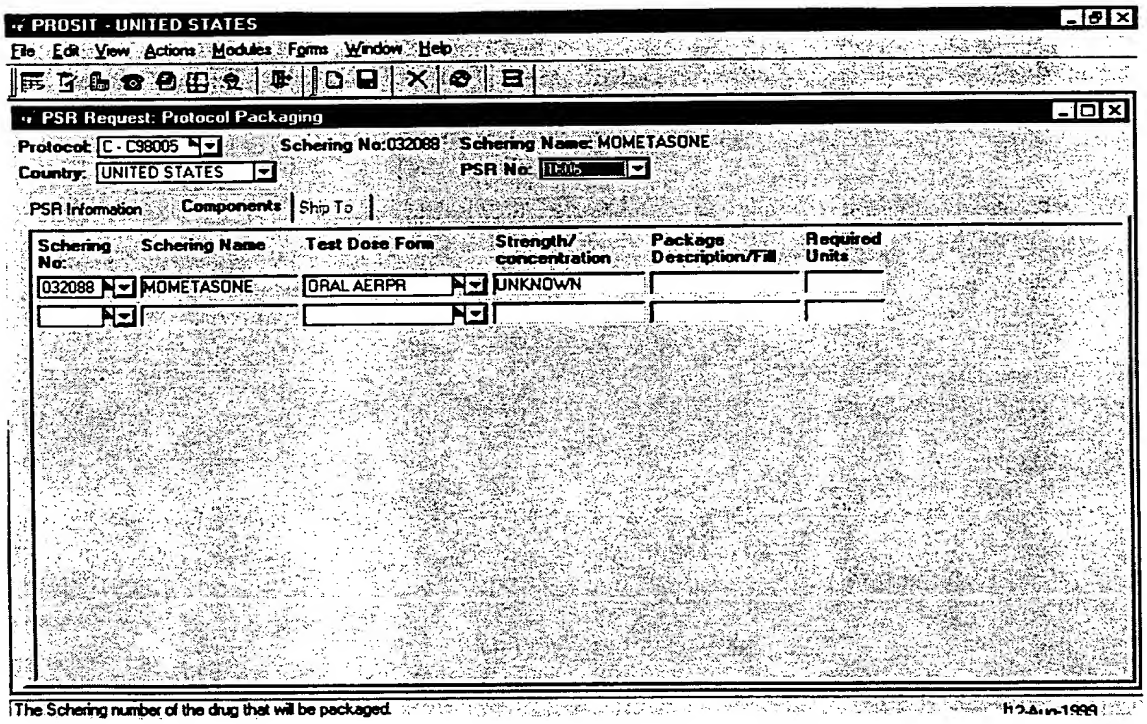


Fig. 53

0055555 / 0050500

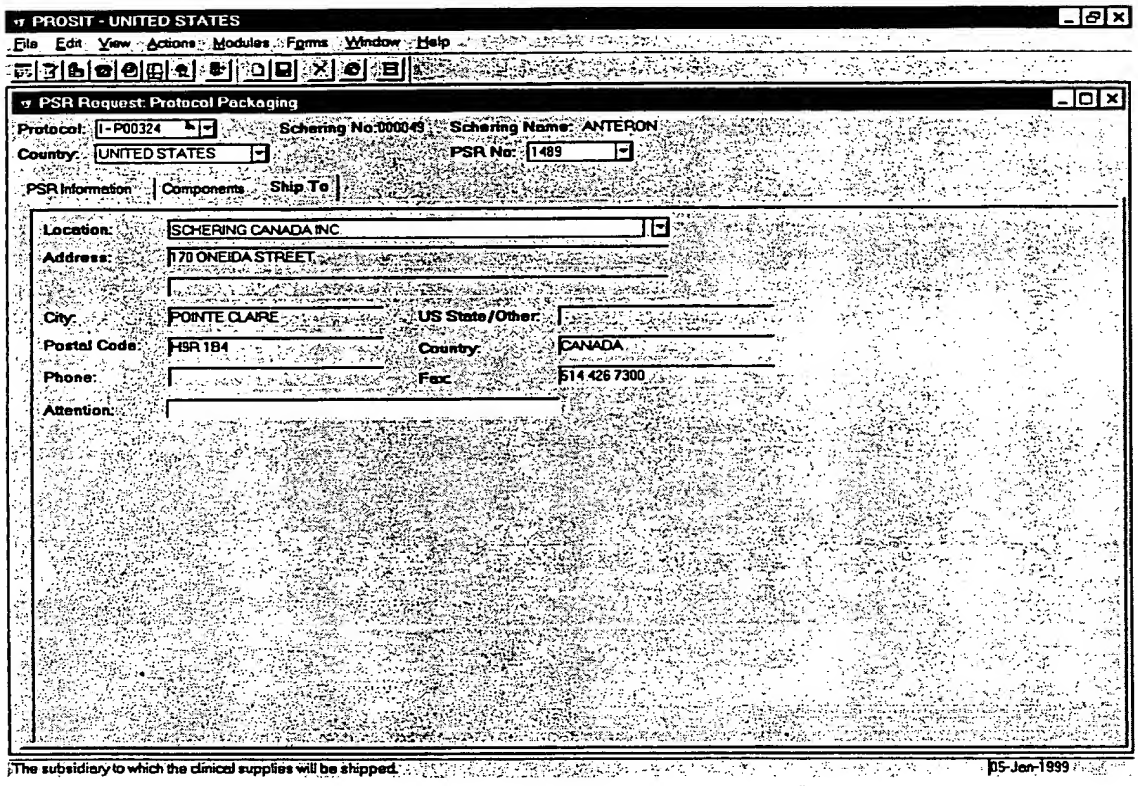


Fig. 54

0009600.7555950

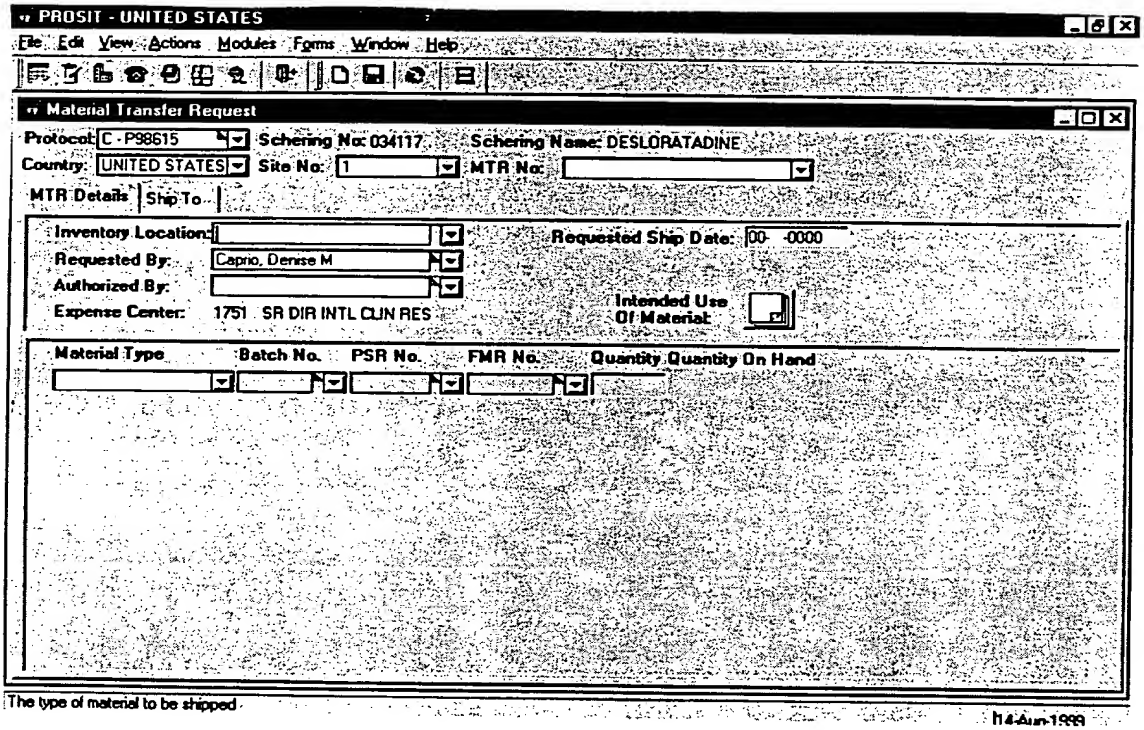


Fig. 55

05555557.0200

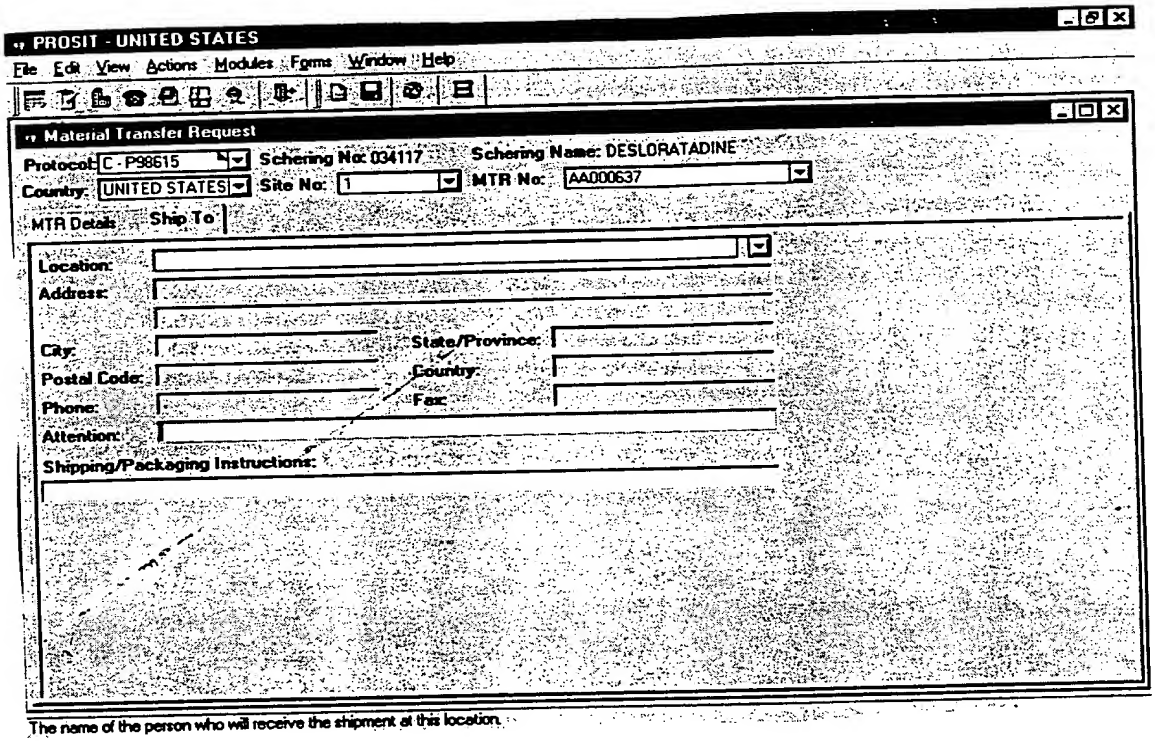


Fig. 56

05555-05000

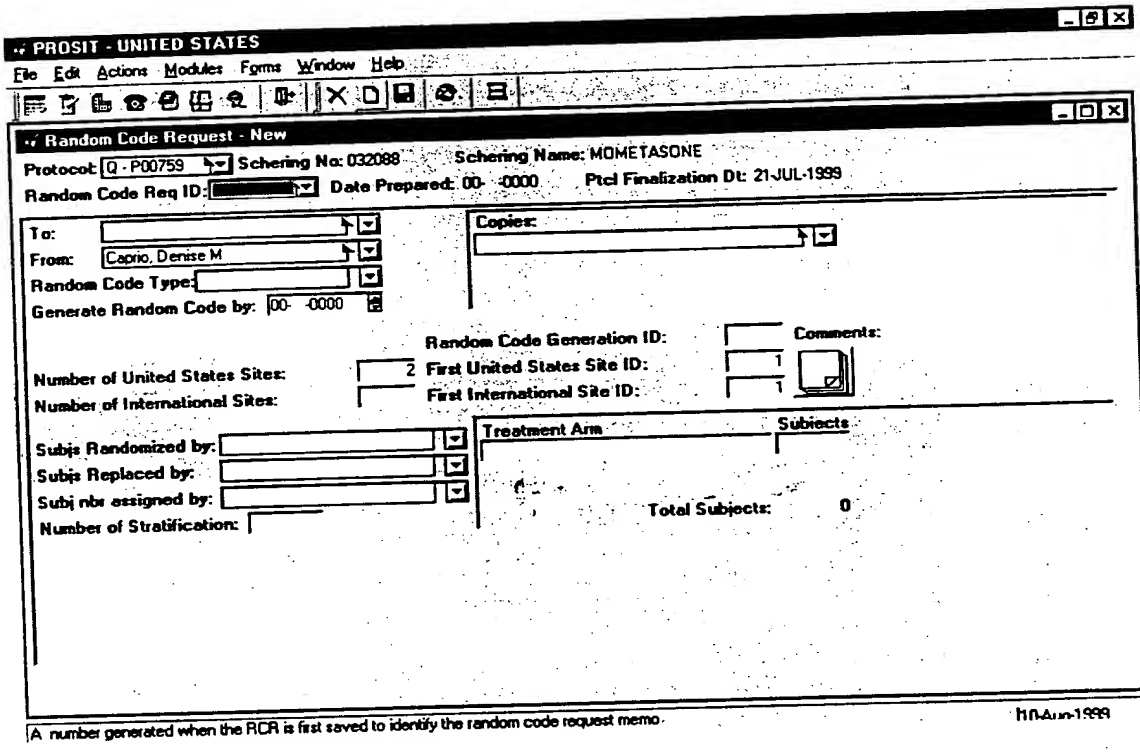


Fig. 57

5955960

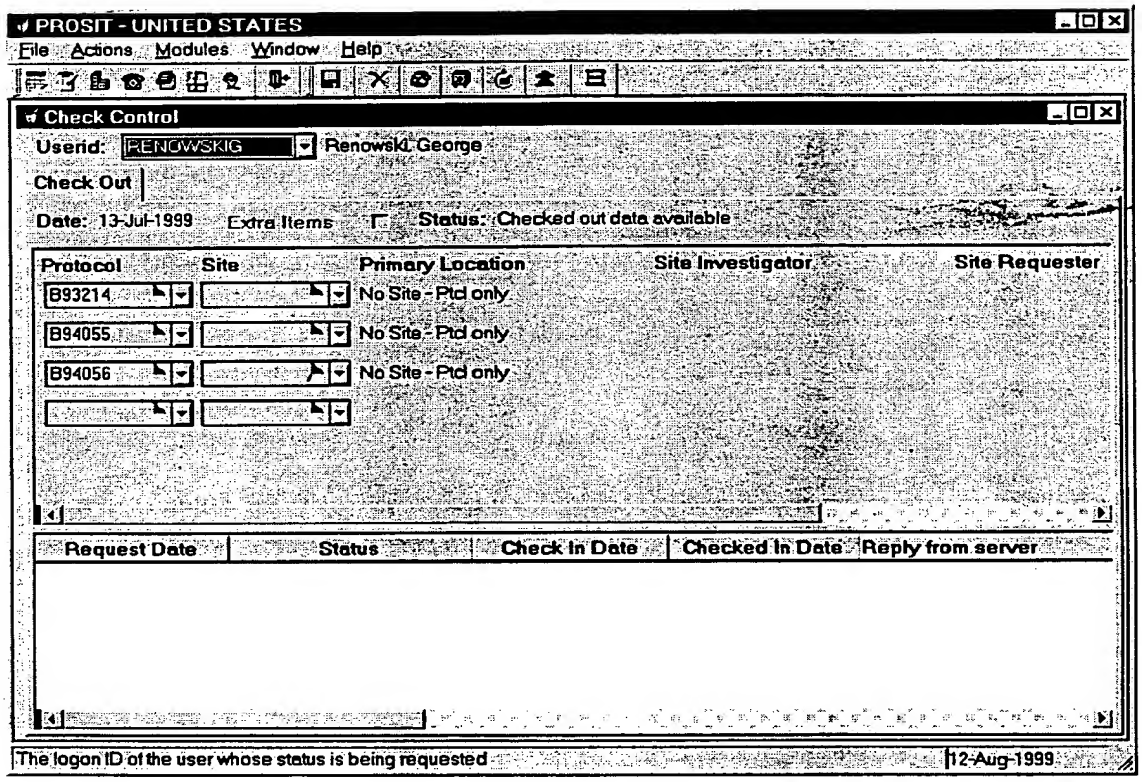
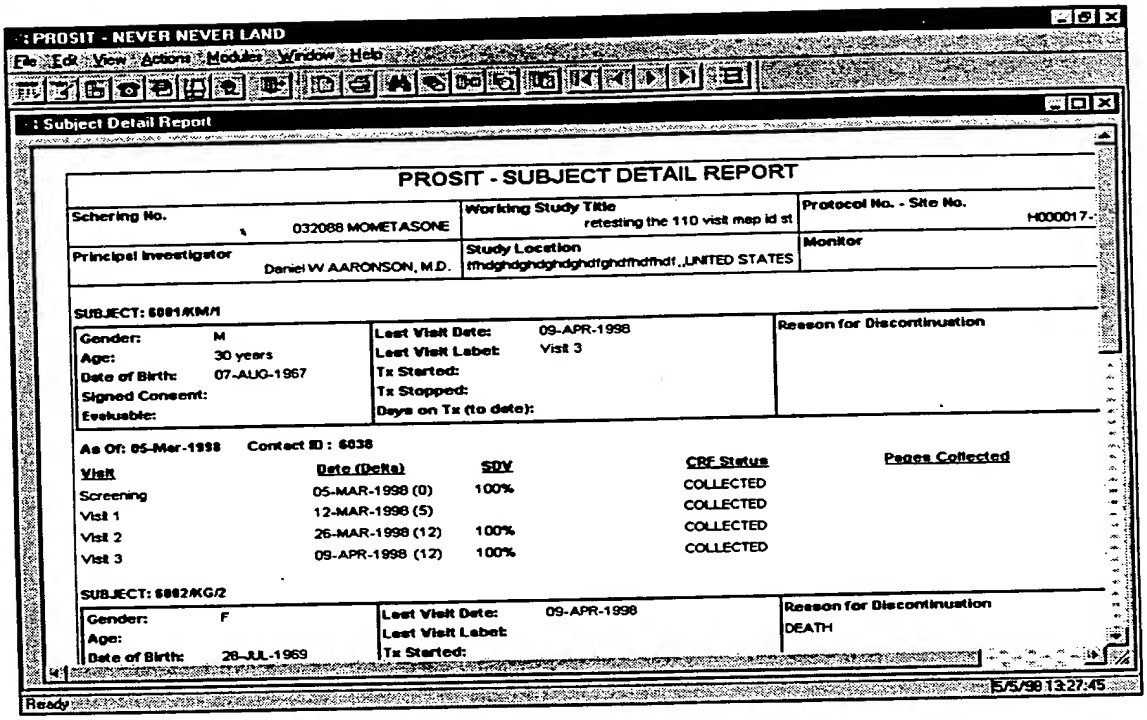


Fig. 58

05550709

SUBJECT DETAIL REPORT



F.5.59

0095053-0095053

QUERYING

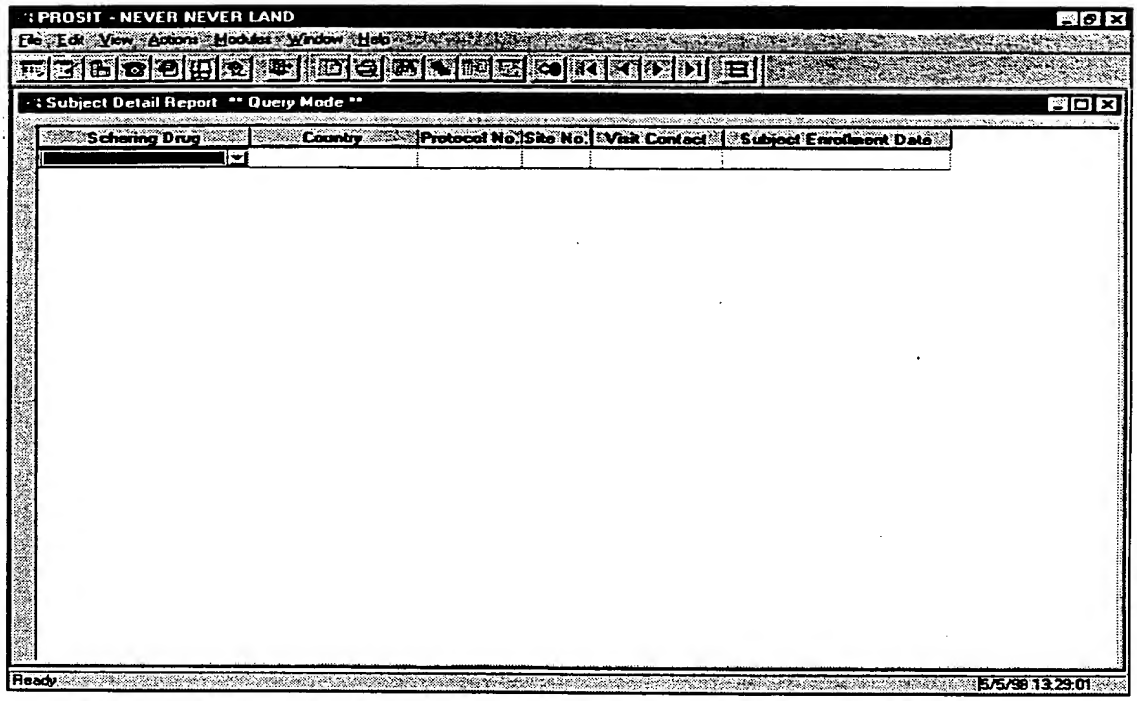


Fig. 60

09506650 "95550

SUBJECT SUMMARY REPORT

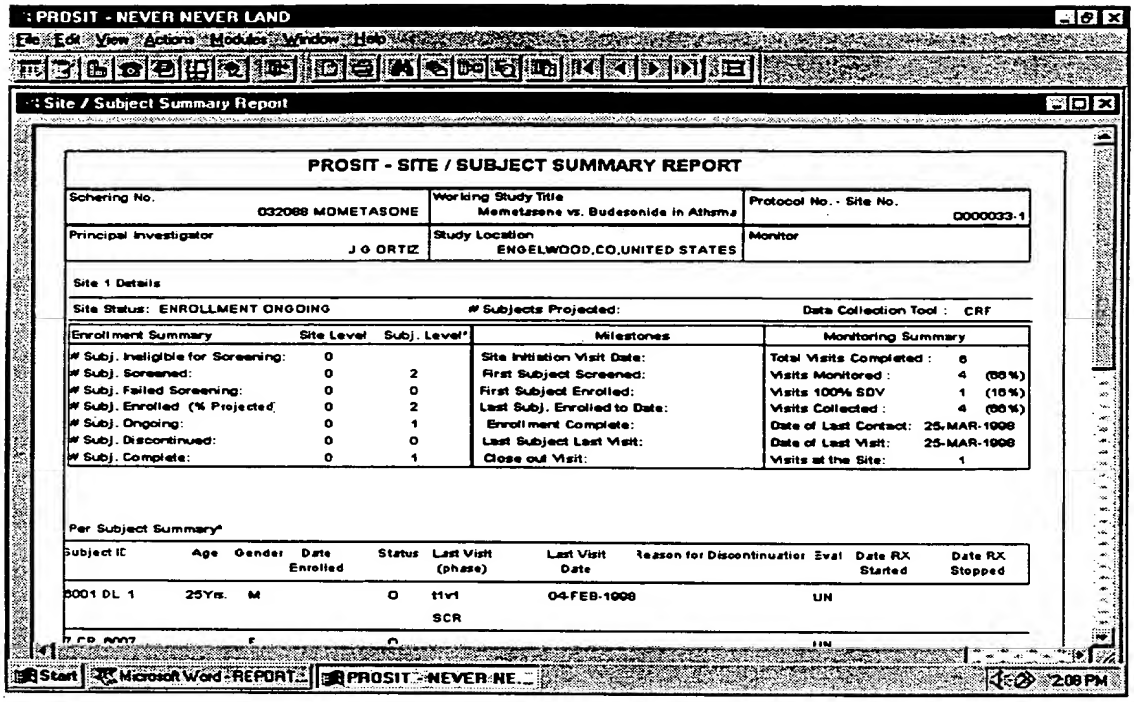


Fig. 61

0055567-0055900

MONITORING STATUS REPORT

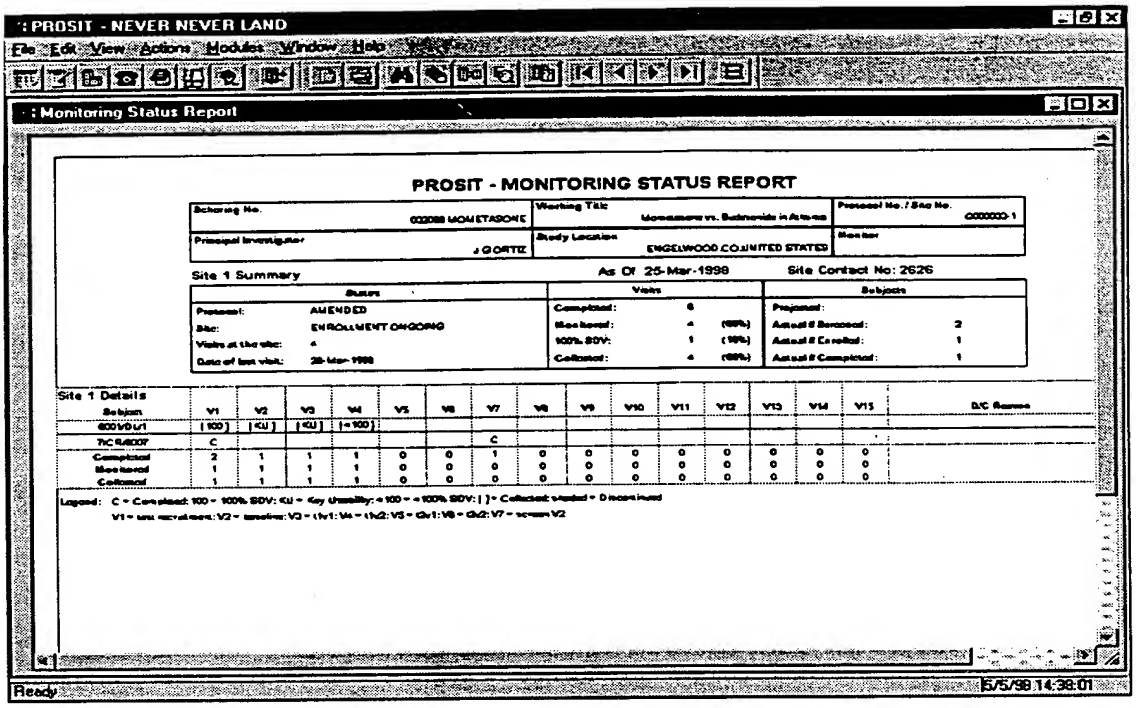
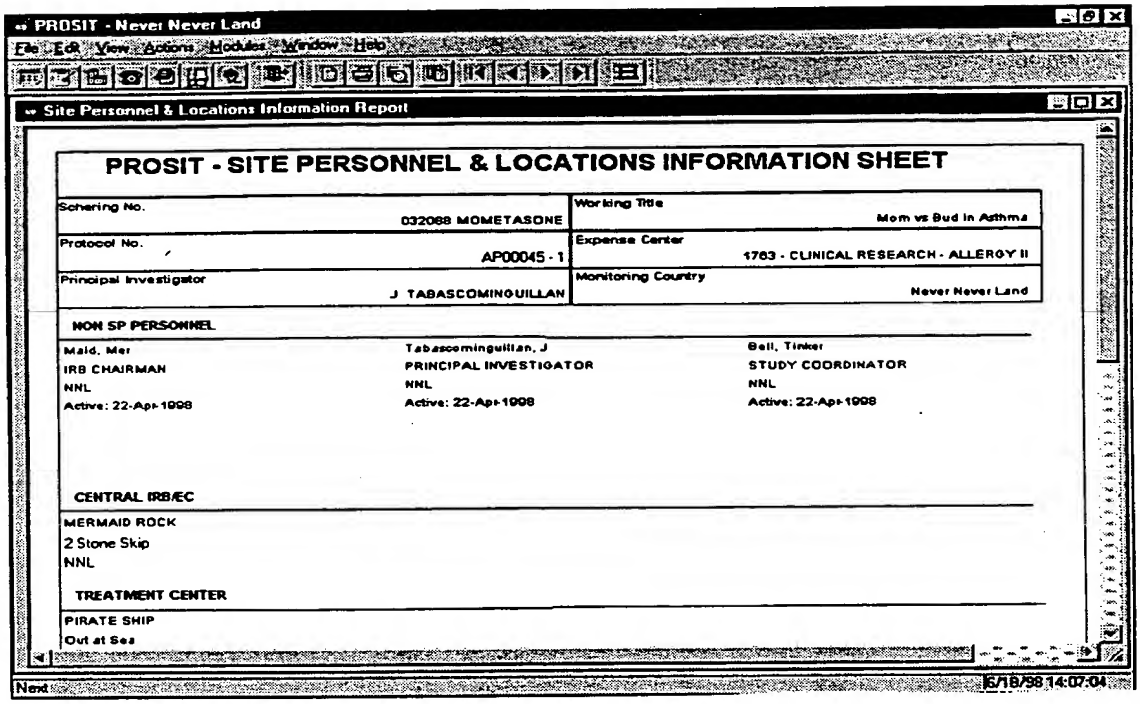


Fig. 62

0090609 .7990595.0

SITE PERSONNEL AND LOCATION REPORT



0555567-0560

Fig. 63

CONTACT INFORMATION REPORT

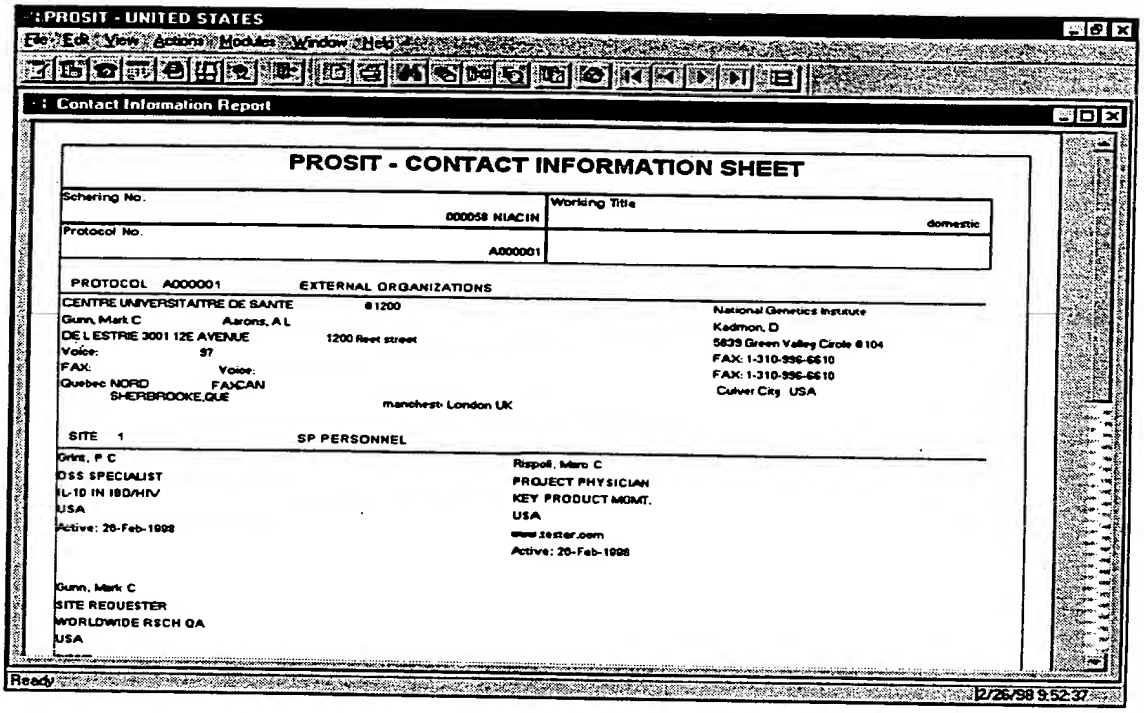


Fig. 64

0056597 0056597

FORMS

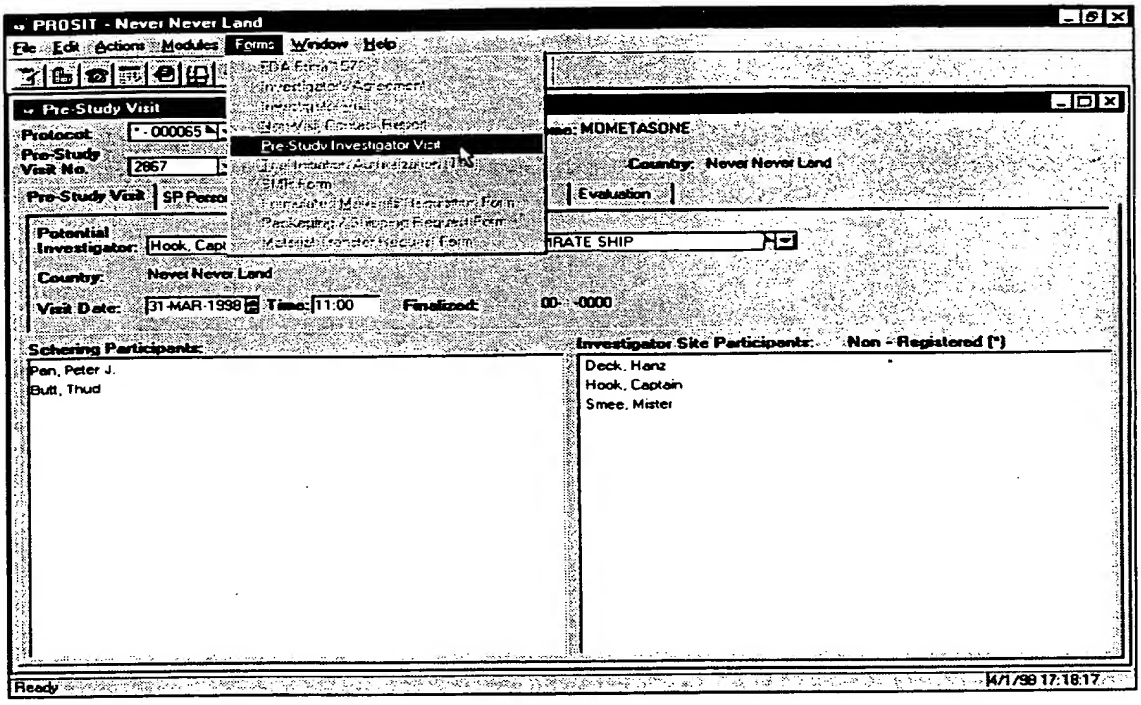


Fig 65

0055550